DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 868

[Docket No. 2007N–0019]

Medical Devices; Anesthesiology Devices; Oxygen Pressure Regulators and Oxygen Conserving Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing a proposed rule to reclassify pressure regulators for use with medical oxygen, currently class I devices included in the generic type of device called pressure regulator, into class II, subject to special controls in the form of a guidance document. Pressure regulators for use with all other medical gases will remain in class I, subject only to general controls. FDA is also proposing to establish a separate classification regulation for oxygen conserving devices (or oxygen conservers), now included in the generic type of device called noncontinuous ventilator. Oxygen conserving devices will continue to be classified in class II, but those that incorporate a built-in oxygen pressure regulator will become subject to the special controls guidance if the rule is finalized. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a class II special controls draft guidance for industry and FDA staff entitled "Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices." The agency is proposing this action because it believes

2007N-0019

NPR 1

that special controls are necessary to provide a reasonable assurance of safety and effectiveness for these devices.

DATES: Submit comments by [*insert date 90 days after the date of publication in the* **Federal Register**]. FDA is proposing that any final rule based on this proposed rule be effective 2 years after the date of its publication in the **Federal Register**.

ADDRESSES: You may submit comments, identified by Docket No. 2007N–0019, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the **ADDRESSES** portion of this document under *Electronic Submissions*.

Instructions: All submissions must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see section XII "What if I Have Comments to the Proposed Rule" heading in the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http: //www.fda.gov/ohrms/dockets/default.htm* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christy Foreman, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240–276–0120.

SUPPLEMENTARY INFORMATION:

I. What Are the Highlights of the Proposed Rule?

The highlights of the proposed rule are as follows:

• FDA is dividing the classification of pressure regulators into two classification regulations.

• Pressure regulators for use with medical gases other than oxygen will remain in class I.

• Pressure regulators for use with medical oxygen will be identified as "oxygen pressure regulators" and will be reclassified into class II (special controls).

• FDA is establishing a separate classification regulation for oxygen conserving devices, which are now included in the generic type of device called noncontinuous ventilators.

• Both noncontinuous ventilators and oxygen conserving devices will remain in class II.

• Oxygen conservers will be classified within their own class according to whether or not the device incorporates a built-in oxygen pressure regulator.

• FDA is establishing a special controls guidance document for oxygen pressure regulators and oxygen conservers that have built-in oxygen pressure regulators entitled "Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices." The main component of the special control guidance will be the American Society of Standards and Materials (ASTM International) Standard G175–03, "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications," published May 2003.

• Manufacturers of oxygen pressure regulators that meet the ASTM standard must label the device "[c]onforms with ASTM G175–03."

• Manufacturers of oxygen conservers with a built-in oxygen pressure regulator that meet the ASTM standard must label the oxygen conserver "[b]uilt-in oxygen pressure regulator conforms with ASTM G175–03."

• Manufacturers of oxygen pressure regulators that meet ASTM G175–03 will be exempt from the premarket notification (510(k)) (section 510(k) of the act (21 U.S.C. 360(k))) requirements, subject to the limitations of exemption in § 868.9 (21 CFR 868.9).

• Manufacturers of oxygen pressure regulators that do not conform with ASTM G175–03 will be required to submit 510(k)s for their devices and

demonstrate that the alternate measures they follow to address the risks identified in the guidance document provide equivalent assurances of safety and effectiveness.

• Although all oxygen conservers will continue to require 510(k) clearance, manufacturers of oxygen conservers with a built-in oxygen pressure regulator may choose to submit an Abbreviated 510(k). This will allow them to address the risks to health associated with use of oxygen pressure regulators by certifying conformance with ASTM G175–03.

II. Which Devices Does the Proposed Rule Affect?

The proposed rule would reclassify pressure regulators that are intended to be used with medical oxygen, currently classified under 21 CFR 868.2700 (Pressure regulator). In addition, the proposed rule would create a separate classification regulation for oxygen conserving devices, currently classified under 21 CFR 868.5905 (Noncontinuous ventilator).

A pressure regulator, sometimes called a pressure-reducing valve, is a medical device used to convert medical gas pressure from a high variable pressure to a lower, more constant working pressure. To illustrate, medical gas is packaged in high pressure cylinders. The gas is released through a part of the cylinder called the post-valve, which functions as an on/off mechanism. When the valve is opened, the cylinder begins to depressurize and medical gas is released at a very high rate of speed. To reduce the pressure and control the gas flow, a pressure regulator is affixed to the post-valve, enabling the user to safely deliver medical gas from the cylinder. This group of devices currently includes pressure regulators for use with medical oxygen.

A noncontinuous ventilator is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing. Because these

devices deliver medical gas to a patient only when needed, they function to conserve the medical gas as well. This group of devices currently includes oxygen conserving devices.

III. What Is the Legal Authority for This Proposed Rule?

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et seq.*), as amended by the Medical Devices Amendments of 1976 (the amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250), and the Medical Devices Technical Corrections Act (MDTCA) (Public Law 108–214), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) establishes three classes of devices, class I (general controls), class II (special controls), and class III (premarket approval). Device classifications depend on the regulatory controls needed to provide reasonable assurance of safety and effectiveness.

Class I devices are devices for which general controls are sufficient to provide reasonable assurance of safety and effectiveness (section 513(a)(1)(A) of the act). Class II devices cannot be classified in class I because general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide such assurance. Special controls may include performance standards, postmarket surveillance, patient registries, the development and dissemination of guidelines, and other measures the agency deems necessary (section 513(a)(1)(B) of the act). Class III devices require each manufacturer of the device to submit to FDA a premarket approval application that includes

information concerning the safety and effectiveness of the device (section 513(a)(1)(C) of the act).

Under section 513(e)(1) of the act, based on new information respecting a device, the agency may, on its own initiative, by regulation change a device's classification. The new information needs to demonstrate that either more regulatory control is needed to provide reasonable assurance of the device's safety and effectiveness or that less regulatory control is sufficient to provide such assurance. Based on the new information discussed in section V of this document, FDA believes that reclassifying pressure regulators for use with medical oxygen from class I to class II, and designating a special control for these devices and for oxygen conserving devices that incorporate a built-in oxygen pressure regulator, is necessary to provide reasonable assurance of the safety and effectiveness of these generic device types.

FDAMA added a new section 510(m) to the act. Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act, if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. FDA has determined that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of oxygen pressure regulators when the manufacturer meets the ASTM standard G175–03 identified in the special controls guidance.

IV. What Is the Regulatory History of These Devices?

In the **Federal Register** of July 16, 1982 (47 FR 31130), FDA issued a final rule classifying oxygen pressure regulators into class II as part of a generic group of devices known as pressure regulators (21 CFR 868.2700) (the 1982 final rule). The 1982 final rule also classified noncontinuous ventilators, which

includes oxygen conservers, into class II (21 CFR 868.5905). At that time, under the existing classification scheme set forth in section 513 of the act, the agency determined that the establishment of a performance standard was appropriate to provide reasonable assurance of the safety and effectiveness of these device types.

Because of a lack of reported adverse events or threats to the public health associated with the use of oxygen pressure regulators, however, the agency later determined that general controls by themselves would provide such assurance. Accordingly, when FDA published a proposed rule on July 28, 1995 (60 FR 38902), which proposed to reclassify 112 generic types of devices from class II to class I, FDA included pressure regulators. FDA received no comments regarding the proposed reclassification of pressure regulators and they were reclassified into class I by final rule on January 16, 1996 (61 FR 1117).

V. What Is the Public Health Concern FDA Is Addressing With This Rule?

Since the January 16, 1996, final rule, FDA has received over 50 adverse event reports associated with the use of pressure regulators when used with oxygen. The majority of the adverse event reports involved oxygen pressure regulators that were made from aluminum. Although the number of events suggests that these occurrences are infrequent, the severity of each event has been significant, including at least one reported death attributable to this problem. In one case, a firefighter suffered third degree burns to the left hand and arm. In a separate incident, another firefighter suffered severe burns to the arms, chest, neck, and face. Overall, these reported incidents show that users of oxygen pressure regulators, including firefighters, emergency medical staff, healthcare workers, and patients, have experienced severe and even fatal

bodily trauma. A comprehensive list of reported adverse events may be found by accessing the agency's Manufacturer and User Facility Device Experience Database (MAUDE) at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm.*

As previously discussed in section II of this document, medical oxygen is packaged in high pressure cylinders. The oxygen is released through a part of the cylinder called the post-valve at approximately 2,200 pounds per square inch. The pressure must be reduced, however, to 50 pounds per square inch so that medical oxygen can safely be delivered to a patient. To reduce the pressure, a regulator is affixed to the pressurized container of gas and is used to control the gas flow. Oxygen regulator fires take place when there is a combustible contaminant (e.g., motor oil, gasoline, hand lotion, cleaning agent) in the flow channel of the oxygen regulator and when the post valve is opened very rapidly. In such situations, the oxygen, on being released from the tank through the post valve, undergoes a rapid expansion and drop in pressure. Upon entering the constricted channels of the oxygen regulator, the gas is recompressed, causing a rapid rise in temperature. If there are combustible contaminants in the flow channels of the oxygen regulator during this rapid rise in temperature, they can catch fire in an environment of relatively high pressure oxygen at high flow rates. The oxygen markedly increases the likelihood and severity of the fire, resulting in serious risk to patients and healthcare workers. Minute shavings of aluminum that collect in aluminum oxygen tanks can also play a role in this process. The shavings can become trapped in the released gas and create friction sparks as they hit the oxygen regulator flow channel walls. Such sparking can cause contaminants to burn in the presence of pressurized oxygen at high rates of flow.

To address the adverse events described previously in this section of the document, FDA and the National Institute for Occupational Safety and Health (NIOSH) issued a public health advisory in February 1999 to fire departments, safety directors, biomedical engineers, nursing homes, emergency transportation services, rescue squads, state emergency medical squad systems, hospital administrators, risk managers, and home health care agencies (Ref. 1). The advisory warned of the potential for explosion or fire associated with pressure regulators when used with medical oxygen. In response to the FDA and NIOSH advisory, many manufacturers stopped producing aluminum regulators, others conducted additional testing, and one voluntarily recalled its products.

VI. How Will More Regulatory Control Reduce the Risks Associated With Pressure Regulators Used With Medical Oxygen?

While the public health advisory served to make manufacturers and users aware of the hazards associated with use of oxygen pressure regulators, it does not address the underlying concerns of safety and effectiveness. To address these concerns, FDA is proposing to reclassify these devices into class II, subject to special controls. Pressure regulators for use with all other medical gases would remain in class I. The proposed special control is a draft guidance document entitled "Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices." The guidance contains labeling recommendations and explains that FDA recognizes ASTM G175–03, "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications." Manufacturers who follow the labeling recommendations and the testing protocols in the guidance would satisfy the special control requirements for oxygen pressure regulators. The draft guidance would also

serve as a special control for oxygen conservers that incorporate a built-in oxygen pressure regulator, devices already classified into class II. Interested persons can obtain the standard from ASTM International, 100 Barr Harbor Dr., West Conshohocken, PA 19428–2959. Further information about ASTM is found at *http://www.astm.org*. (FDA has verified the Web site address, but we are not responsible for subsequent changes to the Web site after this document published in the **Federal Register**.) Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft special controls guidance document.

Preventing fires associated with the use of oxygen pressure regulators requires manufacturers to eliminate active ignition mechanisms in the system or to compensate for their presence. Eliminating the ignition mechanisms is unrealistic, given the conditions of use of medical oxygen pressure regulators, especially in emergency medical service applications where fire and explosion cause the most catastrophic results. Therefore, to mitigate the risks associated with the various potential ignition sources, careful attention to materials selection and established design practice is critical to ensure the fire safety of oxygen regulators.

FDA believes that manufacturers can best validate fire safety design through the use of standard test methods. The consensus standard identified in the special controls guidance describes a two-tier test method for evaluating the ignition sensitivity and fault tolerance of oxygen regulators used for medical and emergency applications. The first test identified by ASTM G175–03 is a rapid pressurization test. It is equivalent to standard 10524, "Pressure Regulators and Pressure Regulators with Flow-Metering Devices for Medical Gas Systems," originally developed by the International Organization for

Standardization (ISO) in 1995. The second test is a promoted ignition test and was developed by ASTM in cooperation with industry, oxygen safety experts, and FDA.

Overall, the standard is intended to account for all potential types of ignition mechanisms present under normal conditions and reasonably foreseeable atypical conditions, including use error. Adherence to the standard can control the risk of fire and explosion by ensuring that manufacturers design regulators to have a low probability of ignition (i.e., greater ignition resistance) and a low consequence of ignition. In this way, the special control can be used as an aid in designing and evaluating the safety of pressure regulators used with medical oxygen. Designation of this guidance document as a special control means that these devices must meet either the specific recommendations of the guidance or some alternate measure that provides equivalent assurance of safety and effectiveness.

FDA is proposing that oxygen pressure regulators that meet the ASTM testing standard identified in the special controls guidance be exempt from premarket notification requirements, subject to the limitations of exemption in § 868.9. If the device did not meet the ASTM testing standard, then the manufacturer would be required to submit a premarket notification that includes information demonstrating that the alternate measure used provides equivalent assurance of safety and effectiveness.

Under the proposed rule, manufacturers of oxygen pressure regulators that meet the ASTM standard would be required to permanently affix to the body of the regulator a statement indicating that the device conforms with ASTM G175–03, "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency

Applications." Similarly, manufacturers of oxygen conserving devices with a built-in oxygen pressure regulator that meet the ASTM standard would also be required to provide labeling that states the oxygen pressure regulator's conformity with ASTM G175–03. In the case of these devices, however, manufacturers would be required to affix the statement to the body of the oxygen conserving device, not the built-in oxygen pressure regulator.

Unlike oxygen pressure regulators, oxygen conserving devices with a built-in oxygen pressure regulator that meets the ASTM standard would not be exempt from premarket notification requirements. This is because the oxygen pressure regulator is just one component of this device and FDA has previously determined that the submission of a 510(k) is necessary to provide reasonable assurance of the safety and effectiveness of oxygen conserving devices. However, manufacturers of oxygen conserving devices with a built-in oxygen pressure regulator who can certify conformance with ASTM G175–03 may be able to submit an abbreviated 510(k) rather than a traditional one.

VII. What Other Alternatives Were Considered by FDA?

FDA considered other alternatives to address the risks associated with use of oxygen pressure regulators, but concluded that reclassifying pressure regulators for use with medical oxygen from class I to class II and designating a special control for these devices, and for oxygen conserving devices that incorporate a built-in oxygen pressure regulator, best addresses the public health and safety concerns associated with these devices in the most efficient and timely manner.

A. Public Outreach

One approach FDA considered was a public outreach campaign. Safety alerts and educational materials, however, would serve only to further identify

the risks to health associated with the use of these devices, but would not serve as a sufficient mitigation measure against them. As discussed previously in this document, FDA, in conjunction with NIOSH, issued a safety advisory alerting industry and consumers of the adverse event reports received by the agency as well as the risks associated with the use of oxygen pressure regulators. The safety alert increased public awareness of the risks to health associated with use of these devices and prompted some manufacturers to modify their materials selection. At the same time, FDA continued to receive reports of adverse events associated with combustion after the safety advisory was issued and concluded, therefore, that public advisories cannot be a substitute for safety controls necessary to ensure the public health.

B. A Mandatory Performance Standard

Another approach FDA considered was to establish a mandatory performance standard. However, a mandatory performance standard may be less flexible than a special controls guidance document in the face of changing market conditions and/or technological circumstances. The proposed rule and special controls guidance document allow for more flexibility. For example, the manufacturer may choose to meet the recommendations of the special controls guidance document or choose to follow some other approach that provides equivalent assurances of safety and effectiveness.

C. Labeling

FDA also considered both mandatory and voluntary labeling as the sole means of addressing the risks associated with these devices. Specifically, FDA considered requiring or suggesting that manufacturers state whether the device conforms with ASTM G175–03. Neither labeling alternative, however, would require that the devices meet a standard or alternate measure providing

equivalent assurances of safety and effectiveness. Thus, FDA concluded that labeling by itself fails to address the underlying potential risks associated with use of these devices.

VIII. How Will FDA Implement a Final Rule?

FDA proposes that any final rule that may issue based on this proposal would become effective 2 years after the date of its publication in the **Federal Register**. Such final rule would apply to all models of oxygen regulators and oxygen conservers with a built-in oxygen pressure regulator. Thus, beginning 2 years after publication of a final rule in the **Federal Register**, all oxygen pressure regulators would become class II devices and would be required to comply with the special controls guidance or an alternative measure that provides equivalent assurances of safety and effectiveness before they could be legally marketed. Once the final rule takes effect, any oxygen pressure regulator that does not meet either the special control or an alternative measure that provides equivalent assurances of safety and effectiveness will be rendered violative under the act and cannot be introduced into interstate commerce. FDA is proposing that a final rule based on this proposal be effective 2 years after the date of its publication in the **Federal Register** in order to safeguard against potential device shortages. Because oxygen pressure regulators are short-lived devices, this 2-year period will allow manufacturers ample time to test and introduce compliant oxygen pressure regulator models, while any existing, non-compliant models are phased-out of the marketplace.

A. Exemption From Premarket Notification (510(k)) Requirements

Upon the effective date of any final rule that issues from this proposal, oxygen pressure regulators would generally be exempt from the premarket notification (510(k)) requirements of the act if they meet the ASTM standard

specified in the special controls guidance and follow the labeling recommendations set forth in the guidance. However, manufacturers of oxygen pressure regulators who use measures other than the ASTM standard identified in the special controls guidance would be required to submit a premarket notification establishing that the alternate measures provide equivalent assurances of safety and effectiveness.

B. Oxygen Conservers

Oxygen conserving devices will remain class II devices, however, those oxygen conservers that have a built-in oxygen pressure regulator will also become subject to the special controls established for the oxygen pressure regulator. As such, beginning on the 2-year effective date, oxygen conservers with a built-in oxygen pressure regulator would become subject to the special controls guidance. Although manufacturers of oxygen conservers with a built-in oxygen pressure regulator that meet the special controls guidance would still need to meet premarket notification requirements, these manufacturers could submit an abbreviated 510(k).

Again, to safeguard against potential device shortages, FDA is proposing that any final rule that issues based on this proposal be effective 2 years after the date of its publication in the **Federal Register**. The 510(k) provides reasonable assurances of safety and effectiveness for these devices.

IX. What Is the Environmental Impact of the Proposed Rule?

The agency has determined under 21 CFR 25.34(b) that this reclassification action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. What Are the Economic Impacts of This Rule?

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Nevertheless, because our projections regarding the number of small entities affected and the economic impact of the proposed rule on small entities are uncertain, the analysis presented in this section of the document, along with this preamble, constitutes the agency's Initial Regulatory Flexibility Analysis (IRFA).

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, including an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is approximately $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not

expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

FDA has reviewed related Federal rules and has not identified any rules that duplicate, overlap, or conflict with this proposed rule.

A. Background

FDA is proposing to reclassify pressure regulators for use with medical oxygen as class II medical devices subject to special controls. The proposed rule also designates a special control for oxygen conserving devices that incorporate a built-in oxygen pressure regulator, which are already in class II. The proposed special control for both types of devices is an FDA draft guidance document that contains labeling recommendations and recommends conformance with an ASTM standard. The agency has received reports of adverse events associated with these devices that have resulted in serious injuries to emergency medical services personnel and patients, including second and third degree burns, and at least one patient death. The majority of adverse event reports associated with these devices involve oxygen pressure regulators made from aluminum. As discussed in greater detail in sections I and II of this document, the agency is proposing these actions in order to provide reasonable assurance of product safety and effectiveness.

B. Affected Entities

This proposed rule would affect manufacturers of oxygen pressure regulators and noncontinuous ventilators (oxygen conservers) that incorporate a built-in oxygen pressure regulator. FDA is aware of 19 manufacturers and approximately 1.5 million to 2 million affected devices currently in use in the emergency medical services and home health care environments. Under this proposed rule, manufacturers of both new and already marketed devices would

be required to demonstrate that their devices conform with either the labeling recommendations and the ASTM standard referenced in the guidance document, or some alternate measure that provides equivalent assurance of safety and effectiveness. Also, under the proposed rule, if an oxygen pressure regulator meets the ASTM G175–03 standard, it would be exempt from premarket notification (or 510(k)) requirements, subject to the limitations on exemptions described in § 868.9. Oxygen pressure regulators that do not meet the ASTM G175–03 standard would not be exempt and manufacturers of these devices would be required to submit a premarket notification (510(k)) and receive an order of substantial equivalence from FDA in order to legally market their devices (sections 510(k) and (m) and 513(f) and (i) of the act; see also proposed § 868.2750(b)(1)). Devices that do not meet the ASTM G175–03 standard and are not found to be substantially equivalent to devices that meet the standard may be adulterated (section 501(f)(1)(B) of the act (21 U.S.C. 351(f)(1)(b))). Finally, under the proposed rule, devices that meet the ASTM G175–03 standard would be required to bear a statement that the device conforms to the standard (proposed §§ 868.2750(b)(2) and 868.5910(b)(3)). All elements of any final rule based on this proposed rule would become effective 2 years after publication in the **Federal Register**.

C. Compliance Requirements and Costs

The major compliance burden associated with this proposed rule is the cost of testing affected devices to demonstrate that they conform with the ASTM standard or submitting a premarket notification demonstrating that an alternate measure provides equivalent assurances of safety and effectiveness. Manufacturers would incur these costs for existing oxygen pressure regulator

models they wish to continue marketing, as well as for new models of oxygen pressure regulators they wish to introduce into interstate commerce.

The standard incorporated by reference in §§ 868.2750(b) and 868.5910(b)(3) is ASTM G175–03, "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators used for Medical and Emergency Applications." This two-tier test is expected to cost between $4,000 and $6,500 for each model of regulator tested, based on the submission of 5 individual test articles. The lower figure represents the estimated cost for many predicate devices, which will not require phase 1 testing because manufacturers have already met this part of the standard in validating their current designs.

An internet search for available information indicated that manufacturers typically produce between 2 and 9 models of these devices. The average number of models produced by manufacturers for which data were available was 4.5 devices per manufacturer. Based on this information, the average one-time cost for testing existing devices is estimated to range from $18,000 ($4,000 per device x 4.5 devices) to $29,250 ($6,500 per device x 4.5 devices) per manufacturer. Applying this range of costs to the 19 known manufacturers yields total one-time testing costs for existing devices that range from $342,000 ($18,000 x 19 manufacturers) to $555,750 ($29,250 x 19 manufacturers).

The actual one-time testing burden may be lower than these estimates suggest because some of these costs have already been incurred by affected entities. Currently, FDA knows of five manufacturers that have voluntarily submitted regulators for additional testing, and three more that plan to do so. However, if either the number of manufacturers or the number of affected

models per manufacturer is significantly greater than assumed in this analysis, the one-time testing burden may be greater than FDA's estimates suggest.

Currently, the agency has no basis for predicting the number or pattern of introduction of new models of affected devices in the future. Therefore, FDA is unable to generate an estimate of annual or recurring testing costs at this time. However, information provided by manufacturers of affected devices indicates that innovation in this market is relatively infrequent. Manufacturers typically rely on a few standard designs that remain on the market for many years with only occasional, minor design changes. It is also the case that, under this proposed rule, not all design changes will require manufacturers to submit devices for additional testing. In particular, additional testing will not be required when design changes do not affect the high pressure areas of the regulator, or components in ignition prone areas. Thus, the agency does not expect that the annual or recurring costs to test affected devices will be significant.

Based on the information presented previously in this document, the agency estimates that the total annualized cost (assuming a 7-percent interest rate over 10 years) to test existing affected devices will range from about $49,000 to $79,000 per year. A sensitivity analysis was also performed (assuming a 3-percent interest rate over 10 years) and suggests a total annualized cost of between $40,000 and $65,000 per year. These figures should be interpreted as lower-bound estimates of the true burden because they do not reflect the annual or recurring costs for manufacturers to test new or redesigned devices. The agency's cost estimates are summarized in table 1 of this document.

TABLE 1.—SUMMARY OF COST ESTIMATES[1]

Total One-Time Cost	Total Annual Cost	Total Annualized Cost[2]	Total Annualized Cost[3]
$342,000 to $556,000	Unknown minimal	$49,000 to $79,000	$40,000 to $65,000

[1] All figures expressed in $US (2005).
[2] At 7 percent interest over 10 years.
[3] At 3-percent interest over 10 years.

FDA does not intend to take enforcement action against end users of devices that fail to meet the special control. Therefore, the proposed rule is not expected to impose any direct costs on end users of these devices. However, although not required under this proposed rule, some manufacturers of affected devices may voluntarily incur costs to recall or replace marketed devices that do not meet the class II special control. FDA has been informed that a significant amount of voluntary recall and replacement has already occurred. Many affected entities, including the manufacturer of the model most commonly associated with the adverse events reported to FDA, have ceased production of regulators made only from aluminum and/or recalled implicated devices. These voluntary actions on the part of manufacturers were taken in response to the issuance of the FDA/NIOSH public health advisory in February 1999, as discussed previously in this document.

Some manufacturers may also incur costs to redesign affected products in response to the special control. The agency currently has no basis for predicting the extent of redesign activities in the future. However, FDA has been informed that 15 affected entities plan to manufacture at least one model of a "brass-only" regulator in the future, and all 19 manufacturers known to the agency have indicated that they will no longer produce regulators with aluminum parts in ignition prone areas. These manufacturers have generally redesigned existing models to be constructed entirely of brass, or to consist of a brass core with an aluminum housing. A search for information on the internet also revealed that only about 10 percent of regulators available on the

market today are made from aluminum. The agency is also aware that manufacturers and distributors of affected devices are advertising the availability of brass only regulators designed in accordance with FDA and NIOSH recommendations. Due to uncertainty regarding the timing and extent of redesign activity that may occur as a result of this proposed rule, the agency is not able to quantify this potential source of compliance costs.

The labeling requirement specified in the proposed rule is not expected to generate a significant new cost burden for affected entities because labeling is already required for all medical devices under 21 CFR part 801. A manufacturer can comply with the requirement by adding to the body of the device a permanent sticker that states the device meets ASTM G175–03. Therefore, FDA believes that this requirement will impose only nominal costs on affected entities.

D. Benefits

The proposed rule is expected to generate benefits due to a reduction in the number of adverse events associated with oxygen regulators. Major categories of costs incurred as a result of these adverse events include: (1) Expenditures for medical treatment of resulting injuries; (2) work, income, and productivity loss; and (3) pain and suffering.

Pressure regulators for use with medical oxygen were reclassified as class I medical devices in January 1996, and FDA received 55 reports of regulators involved with fires and/or explosions between 1993 and 2005. These events resulted in serious injuries to 40 individuals, consisting mainly of burns, typically second and/or third degree burns to the hands, arms, chest, neck and/or face, and at least 1 patient death. These figures imply an average of 4 adverse

events (55 adverse events/13 years = 4.23) and 3 cases of serious injury to individuals (40 serious injuries/13 years = 3.08) annually.

The U.S. Consumer Product Safety Commission (CPSC) collects information on various types of consumer product-related injuries and generates estimates of the associated costs. In a 1998 report (Ref. 2), the CPSC presents estimates of the: (1) Lifetime medical costs; (2) total of short-term and long-term victim work-loss; and (3) pain and suffering cost per survivor of consumer-product related injury, both by the nature of injury and body part injured. These cost estimates are further categorized by type of treatment received, e.g., non-hospital admitted, which typically includes treatment in a physician's office or emergency department, and hospital admitted, or inpatient care. The CPSC estimates are based on the Revised Injury Cost Model and are designed to be representative of the costs of treating consumer product related injuries on average, adjusting for various demographic and other factors. The figures in the CPSC report are expressed in 1995 dollars, and were adjusted to 2005 dollars based on inflation statistics reported by the U.S. Department of Labor. The CPSC cost estimates used in this analysis are summarized in table 2 of this document.

TABLE 2.—COSTS OF TREATING BURN INJURIES BY THE NATIONAL ELECTRONIC INJURY SURVEILLANCE SYSTEM (NEISS) INJURY DIAGNOSIS CODE AND TYPE OF TREATMENT (PER OCCURRENCE)[1]

NEISS Injury Diagnosis Code	Treatment Costs	Income Loss	Pain and Suffering	Total Costs
a. Non-Hospitalized—Emergency Department Treatment				
51: Burns, thermal	$750	$1,700	$24,700	$27,150
84: 25% to 50% of body	$1000	$1,000	$8,300	$10,300
b. Admitted/Inhospital Treatment				
51: Burns, thermal	$39,300	$36,800	$177,200	$253,300
84: 25% to 50% of body	$49,400	$54,400	$190,600	$294,400

[1] All figures expressed in $US (2005).

The NEISS diagnosis codes reflected in tables 2a and 2b of this document were chosen for this analysis because they are the most relevant given the type

of injuries typically cited in the adverse event reports. The lower figures in table 2a of this document are indicative of the costs of treating relatively minor burn injuries associated with the less serious oxygen pressure regulator adverse events. The higher figures in table 2b of this document reflect the costs of treating severe injuries associated with the more serious adverse events. The majority of adverse events reported to the agency appear to fall into the latter, more serious, category.

Based on the cost estimates obtained from the CPSC report and using the average number of reported adverse events (4), a range of annual benefits estimates (reflecting medical treatment costs, work/income loss and pain and suffering avoided) can be generated. The estimated annual benefits associated with this proposed rule are presented in table 3 of this document.

TABLE 3.—SUMMARY OF TOTAL ANNUAL BENEFITS ESTIMATES[1]

NEISS Injury Diagnosis Code	Emergency Department Treatment	Admitted/Inhospital Treatment
51: Burns, thermal	$109,000	$1 million
84: 25% to 50% of body	$41,000	$1.2 million

[1] All figures expressed in $US (2005).

Based on this information, the estimated annual benefits of this proposed rule are expected to be between $41,000 and $1.2 million. These figures should be interpreted as conservative, lower bound estimates of the potential benefits of this proposed rule for a number of reasons. First, the adverse event reports upon which these estimates are based were submitted voluntarily, and the agency is aware that many adverse events are not reported under the current voluntary systems. A 1997 General Accounting Office report (Ref. 3) on FDA's reporting systems found evidence of significant under-reporting of adverse events associated with medical devices. Thus, the risks associated with affected devices, as well as the potential benefits of the proposed rule, may be significantly greater than the agency's estimates suggest. Second, because

of a lack of data, no attempt was made to estimate the value of property damage associated with the adverse events reported. In one case, cited in section V of this document, the interior compartment of an ambulance was incinerated as a result of an oxygen pressure regulator fire/explosion, resulting in a loss of valuable property. Finally, the estimates presented in table 3 of this document do not reflect the potential benefits of any reduction in mortality risk resulting from oxygen pressure regulator fires and/or explosions. Voluntary reports of adverse events submitted to the agency indicate that at least one death was associated with oxygen pressure regulator fires and/or explosions during the period 1993 to 2005. The agency expects that this proposed rule would significantly reduce the risk of similar events in the future.

If, however, recent actions on the part of manufacturers (since issuance of the 1999 public health advisory) have already reduced the risk of oxygen regulator fires and explosions, FDA's estimates may overstate the potential benefits of this proposed rule to some extent.

E. Impact on Small Entities

FDA believes that it is unlikely that the proposed rule would have a significant economic impact on a substantial number of small entities. The agency knows of 19 firms currently manufacturing the affected devices. Some of the entities affected by this proposed rule meet the Small Business Administration's (SBA) criteria characterizing small entities in the relevant industry category. The North American Industry Classification System (NAICS) code for manufacturers of oxygen pressure regulators is 339112—*Surgical and Medical Instrument Manufacturing*. According to the SBA criteria, a small firm in this industry sector has fewer than 500 employees (Ref. 4.) A review of

available data, including the internet sites of Dun and Bradstreet® (*http://www.dnb.com*) and ThomasRegister® (*http://www.thomasnet.com*) (Refs. 5 and 6), revealed that 12 manufacturers of these devices had fewer than 500 employees and would therefore be considered small entities. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**. Thus, a majority, or approximately 63 percent [(12 / 19) x 100], of entities affected by this proposed rule would qualify as small entities.

An FDA review of available data found that the average annual revenue of small entities affected by this rule is approximately $123 million (Refs. 5 and 6). The total annualized cost for this proposed rule (assuming a 7-percent interest rate) ranges from $49,000 to $79,000, and an average annualized cost per affected entity ranging from $2,600 ($49,000 / 19 entities) to $4,200 ($79,000 / 19 entities). A sensitivity analysis was also performed (assuming a 3-percent interest rate) and suggests a total annualized cost of between $40,000 and $65,000. These estimates correspond to an average annualized cost of between $2,100 and $3,400 per affected entity. Thus, the average annualized cost of the proposed rule, expressed as a percentage of average annual revenues for affected small entities, ranges from 0.002 [($2,100 / $123 million) x 100 = 0.0017] percent to 0.003 [($4,200 / $123 million) x 100 = 0.0034] percent. This information is summarized in table 4 of this document.

TABLE 4.—SUMMARY OF SMALL BUSINESS IMPACTS[1]

Interest Rate	Total Annualized Cost	Average Annualized Cost	Average Annualized Cost as a Percentage of Average Revenue
7%	$49,000 to $79,000	$2,600 to $4,200	0.002% to 0.003%
3%	$40,000 to $65,000	$2,100 to $3,400	0.002% to 0.003%

[1] All figures expressed in $US (2005).

As discussed earlier in this section of the document, the economic impacts of the proposed rule are not expected to be significant. Therefore, the agency

believes that the rule will not have a significant economic impact on a substantial number of small entities. However, due to uncertainty with respect to the size distribution of manufacturers, the number of affected devices that will be introduced in the future, and the overall impact of the rule on small entities, the agency is unable to certify that there would be no significant economic impact on a substantial number of small entities. Therefore, FDA specifically requests detailed industry comment on the number of affected small entities and the potential economic impact of the proposed rule on affected entities.

A number of provisions of the proposed rule would help to minimize the economic impact of the rule, particularly for affected small entities. For example, affected devices would not be required to comply with the special control until 2 years after publication of any final rule based on this proposal. This time period would allow manufacturers an opportunity to make any necessary design changes, test products, and modify labeling. In addition, this should help prevent product shortages and thereby minimize the potential for significant fluctuation in the price of the affected devices.

In addition, manufacturers who choose not to meet the ASTM G175–03 standard referenced in the special control would have the option to demonstrate, through the pre-market notification (510(k)) process, that their devices are substantially equivalent to devices that meet the standard. This provides manufacturers of the affected devices with more flexibility in complying with the special controls necessary to provide reasonable assurances of the safety and effectiveness of these devices.

FDA has considered several regulatory alternatives to this proposed rule in addition to taking no regulatory action at all. The alternatives are: (1) Public

outreach, (2) adoption of a mandatory performance standard, and (3) product labeling alone. Taking no action was deemed inappropriate because the adverse event reports received by the agency indicate that these devices present a clear risk to public health and safety. Similarly, although public outreach through the FDA/NIOSH safety advisory alerted consumers to the risks to health associated with the use of oxygen pressure regulators, it did not provide a sufficient means for mitigating those risks.

A mandatory performance standard was rejected in favor of the special control guidance document for several reasons. A mandatory performance standard may be less flexible than a special controls guidance document in the face of changing market conditions and technological circumstances. The special controls guidance document allows for some flexibility. For example, the manufacturer may meet either the recommendations of the special controls guidance document or some other measure that provides equivalent assurances of safety and effectiveness. FDA believes that the proposed rule will address the risks to health presented by these devices without significantly disrupting the market for these devices.

FDA also considered both mandatory and voluntary labeling alone as the special control. We rejected these options because labeling provisions alone, whether mandatory or voluntary, would not ensure that the devices meet some accepted industry standard or other equivalent measure and, therefore, would not provide adequate assurances of product safety and effectiveness. Furthermore, a voluntary labeling provision would leave the agency without an effective monitoring and enforcement mechanism. FDA believes that reclassifying pressure regulators for use with medical oxygen from class I to class II and designating a special control for these devices, and for oxygen

conserving devices that incorporate a built-in oxygen regulator, best addresses the public health and safety concerns associated with these devices in the most efficient and timely manner.

XI. Are There Any Paperwork Burdens Created by the Proposed Rule Under the Paperwork Reduction Act of 1995?

No. The labeling statements that would be required by this regulation are "public disclosure[s] of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public * * *" (5 CFR 1320.3(c)(2)). Accordingly, FDA concludes that the labeling requirements in this proposed rule are not subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

XII. What if I Have Comments to the Proposed Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XIII. What Are the References for the Proposed Rule?

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA and NIOSH Public Health Advisory: Explosions and Fires in Aluminum Oxygen Regulators, February 1999.

2. U.S. Consumer Product Safety Commission, Estimating the Cost to Society of Consumer Product Injuries: The Revised Injury Cost Model, January 1998.

3. U.S. General Accounting Office, Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems with Approved Devices, January 1997.

4. U.S. Small Business Administration, Office of Size Standards, Table of Size Standards, Sector 62—Health Care and Social Assistance, 2002.

5. Dun and Bradstreet®, available online at *http://www.dnb.com.*

6. Thomas Register®, available online at *http://www.thomasnet.com.*

List of Subjects in 21 CFR Part 868

Incorporation by reference, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 868 be amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. Section 868.2700 is amended by revising paragraph (a) to read as follows:

§ 868.2700 Pressure regulator.

(a) *Identification.* A pressure regulator is a device, often called a pressure-reducing valve, that is intended for medical purposes and that is used to convert a medical gas pressure from a high variable pressure to a lower, more

constant working pressure. This device does not include pressure regulators for use with medical oxygen.

* * * * *

3. Section 868.2750 is added to supbart C to read as follows:

§ 868.2750 Oxygen pressure regulator.

(a) *Identification.* An oxygen pressure regulator is a device, often called a pressure-reducing valve, that is intended for medical purposes and that is used to convert medical oxygen pressure from a high variable pressure to a lower, more constant working pressure.

(b) *Classification.* (1) Class II (special controls). The special control for this device is FDA's "Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices." See § 868.1(e) for the availability of this guidance document. If the device meets American Society for Testing and Materials Standard (ASTM) G175–03, "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications," the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 868.9. ASTM G175–03, "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications" is incorporated by reference.

(2) If the device conforms with American Society for Testing and Materials Standard (ASTM) G175–03, "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications," the device must bear a statement permanently affixed to the body of the regulator that states: "Conforms with ASTM G175–

03." ASTM G175–03, "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications" is incorporated by reference.

4. Section 868.5905 is amended by revising paragraph (a) to read as follows:

§ 868.5905 Noncontinuous ventilator.

(a) *Identification.* A noncontinuous ventilator is a device intended to deliver intermittently an aerosol to a patient's lungs or to assist a patient's breathing. This classification includes intermittent positive pressure breathing devices, continuous positive airway pressure devices, and bilevel positive airway pressure devices.

* * * * *

5. Section 868.5910 is added to subpart F to read as follows:

§ 868.5910 Oxygen conserver.

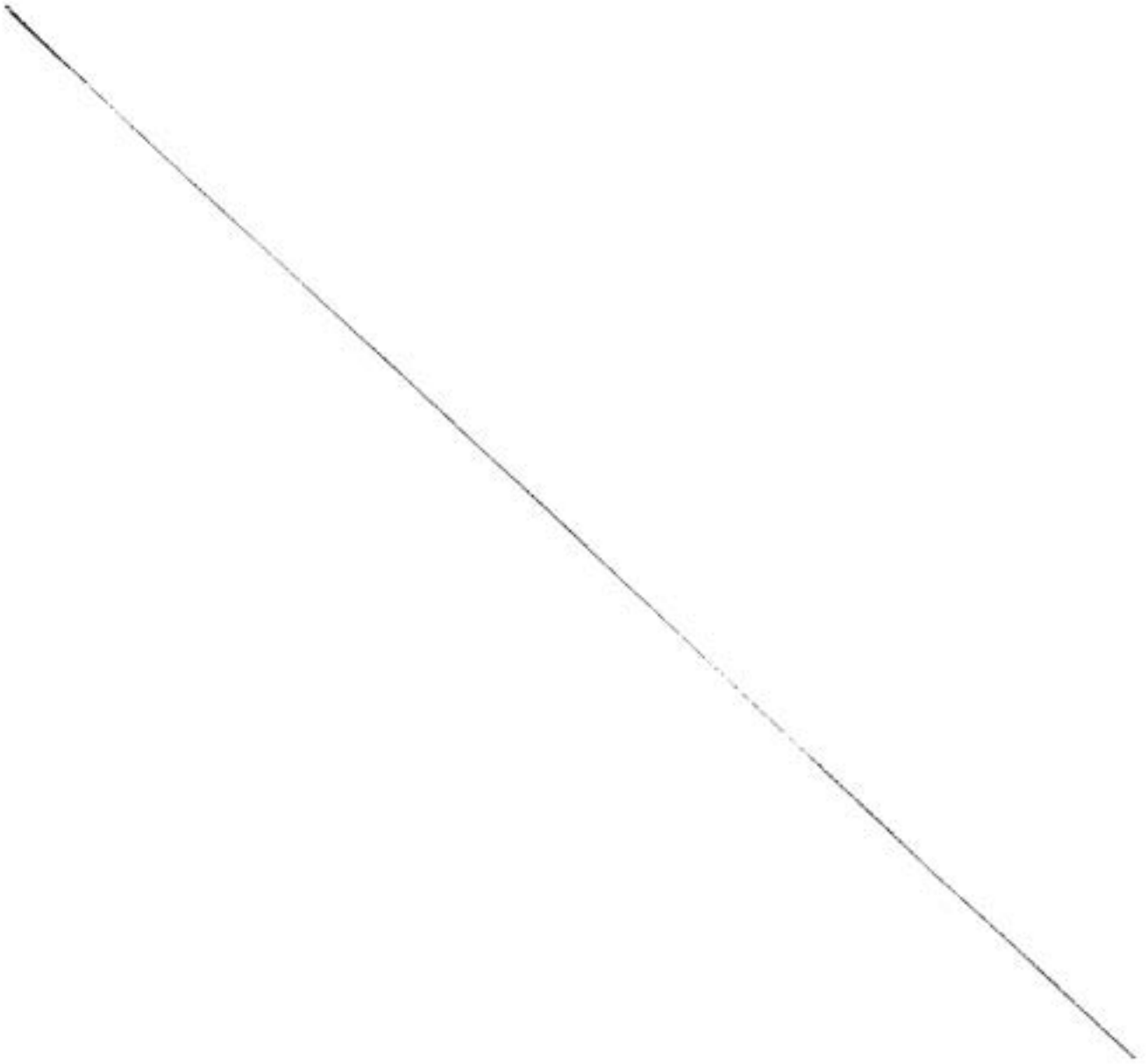
(a) *Oxygen conserver*—(1) *Identification.* An oxygen conserver is a device intended to conserve oxygen delivered to a patient, but does not incorporate a built-in oxygen pressure regulator.

(2) *Classification.* Class II (performance standards).

(b) *Oxygen conserver with built-in oxygen pressure regulator*—(1) *Identification.* An oxygen conserver with built-in oxygen pressure regulator is a device intended to conserve oxygen delivered to a patient and incorporates a built-in oxygen pressure regulator.

(2) *Classification.* Class II (special controls). The special control for an oxygen conserver with built-in oxygen pressure regulator is FDA's "Class II Special Controls Guidance Document: Oxygen Pressure Regulators and Oxygen Conserving Devices." See § 868.1(e) for the availability of this guidance document.

(3) If the built-in oxygen pressure regulator conforms with ASTM G175–03, "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications," then a statement must be permanently affixed to the body of the oxygen conserver that states: "Built-in oxygen pressure regulator conforms with ASTM G175–03." ASTM G175–03, "Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications" is incorporated by reference.



Dated: 2/8/06
February 8, 2007.

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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