2006–19–12 Boeing: Amendment 39–14769. Docket No. FAA–2005–22874; Directorate Identifier 2005–NM–173–AD.

Effective Date

(a) This AD becomes effective October 30, 2006.

Affected ADs

(b) None.

Applicability

(c) This AD applies to Boeing Model 777–200 and –300 series airplanes, certificated in any category; as identified in Boeing Special Attention Service Bulletin 777–54–0021, Revision 1, dated March 16, 2006.

Unsafe Condition

(d) This AD results from a report that several discolored fairing lower webs and some damaged/deteriorated insulation blankets were found in the aft fairings of engine struts. We are issuing this AD to prevent cracking of lower webs of the aft fairings, which could result in flammable hydraulic fluid leaking onto or near an ignition source, and possibly result in an uncontrollable fire in the engine strut area.

Compliance

(e) You are responsible for having the actions required by this AD performed within the compliance times specified, unless the actions have already been done.

Inspection, Installation, and Replacement Actions

(f) Except as provided by paragraph (g) of this AD: Within 12 months after the effective date of this AD, do the actions specified in paragraphs (f)(1), (f)(2), (f)(3), and (f)(4) of this AD in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–54–0021, Revision 1, dated March 16, 2006.

(1) Do a general visual inspection of the lower web of the aft fairing for any discoloration and do any related investigative action.

(2) Do a general visual inspection of the heat shield castings for any damage (crack(s), dent(s), gouge(s), warpage, fretting, or missing/loose nutplates).

(3) Install gap cover strips on the heat shield pans.

(4) Replace insulation blankets on the heat shield pans with new insulation blankets.

Repair Instructions

(g) If any damage, discoloration, heat damage, or crack is found during any inspection required by this AD: Before further flight, do all applicable corrective actions in accordance with a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, or in accordance with the Accomplishment Instructions of Boeing Special Attention Service Bulletin 777–54–0021, Revision 1, dated March 16, 2006.

Previously Accomplished Actions

(h) Actions done before the effective date of this AD in accordance with Boeing Special Attention Service Bulletin 777–54–0021, dated June 23, 2005, are acceptable for compliance with the requirements of paragraph (f) of this AD, except where the service bulletin does not provide an International Annealed Copper Standard (ICAS) value for determining the results of the inspection for heat damage, the maximum acceptable ICAS value is 42 percent.

Alternative Methods of Compliance (AMOCs)

(i)(1) The Manager, Seattle ACO, FAA, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with 14 CFR 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair required by this AD, if it is approved by an Authorized Representative for the Boeing Commercial Airplanes Delegation Option Authorization Organization who has been authorized by the Manager, Seattle ACO, to make those findings. For a repair method to be approved, the repair must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

Material Incorporated by Reference

(j) You must use Boeing Special Attention Service Bulletin 777–54–0021, Revision 1, dated March 16, 2006, to perform the actions that are required by this AD, unless the AD specifies otherwise. The Director of the Federal Register approved the incorporation by reference of this document in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124–2207, for a copy of this service information. You may review copies at the Docket Management Facility, U.S. Department of Transportation, 400 Seventh Street SW., Room PL–401, Nassif Building, Washington, DC; on the Internet at *http://dms.dot.gov*; or at the National Archives and Records Administration (NARA). For information on the availability of this material at the NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

Issued in Renton, Washington, on September 13, 2006.

Kevin M. Mullin,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 06–8122 Filed 9–22–06; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 807, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, and 892

[Docket No. 2006N–0335]

Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending certain classification regulations for reprocessed single-use devices (SUDs) whose exemption from premarket notification (510(k)) requirements have been terminated and other reprocessed SUDs already subject to premarket notification for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), are necessary in a 510(k). Elsewhere in this issue of the **Federal Register**, we are publishing a companion proposed rule, under FDA's usual procedures for notice and comment, to provide a procedural framework to finalize the rule in the event we receive any significant adverse comment and withdraw the direct final rule. This action codifies actions taken in previous **Federal Register** notices in accordance with MDUFMA.

DATES: This rule is effective February 7, 2007. Submit written or electronic comments by December 11, 2006. If we receive no significant adverse comments within the specified comment period, we intend to publish a document confirming the effective date of the final rule in the **Federal Register** within 30 days after the comment period on this direct final rule ends. If we receive any timely significant adverse comment, we will withdraw this final rule in part or in whole by publication of a document in the **Federal Register** within 30 days after the comment period ends.

ADDRESSES: You may submit comments, identified by Docket No. 2006N–0335, 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 *Electronic Submissions* portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) 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 the ''Comments'' heading of 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(s), 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: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190, ext. 143.

SUPPLEMENTARY INFORMATION:

I. What Is the Background of the Rule?

On October 26, 2002, MDUFMA (Public Law 107–250), amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 510(o) (21 U.S.C. 360(o)), which provided new regulatory requirements for reprocessed SUDs. According to this provision, in order to ensure that reprocessed SUDs are substantially equivalent to predicate devices, 510(k)s for certain reprocessed SUDs identified by FDA must include validation data. These required validation data include cleaning and sterilization data, and functional performance data demonstrating that each SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

Before enactment of the new law, a manufacturer of a reprocessed SUD was required to obtain premarket approval or premarket clearance for the device, unless the device was exempt from premarket submission requirements. Under MDUFMA, some previously exempt reprocessed SUDs are no longer exempt from premarket notification requirements. Manufacturers of these identified devices were required to submit 510(k)s that included validation data specified by FDA. Reprocessors of certain SUDs already subject to cleared 510(k)s were also required to submit the validation data specified by the agency.

A. Definitions

Under section 201(ll)(2)(A) of the act (21 U.S.C. 321(ll)(2)(A)), a reprocessed SUD is defined as an ''original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition.'' FDA is amending § 807.3 (21 CFR 807.3) by adding paragraph (t) to incorporate this definition into the regulations.

Reprocessed SUDs are divided into three groups: (1) Critical, (2) semicritical, and (3) noncritical. The first two categories are set forth in the act and all three reflect a categorization scheme recognized in the industry (Ref. 1). In the **Federal Register** of April 30, 2003 (68 FR 23139), FDA describes in more detail the development of this scheme and its use in the implementation of section 510(o) of the act. The act defines critical and semicritical reprocessed single use devices at section 201(mm) as amended by MDUFMA. FDA defined noncritical devices in the **Federal Register** of April 30, 2003. The definitions are as follows:

- A critical reprocessed SUD is intended to contact normally sterile tissue or body spaces during use.
- A semicritical reprocessed SUD is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body.
- A noncritical reprocessed SUD is intended to make topical contact and not penetrate intact skin.

B. Critical and Semicritical Reprocessed SUDs Previously Exempt from Premarket Notification

MDUFMA required FDA to review the critical and semicritical reprocessed SUDs that were previously exempt from premarket notification requirements and determine which of these devices required premarket notification to ensure their substantial equivalence to predicate devices. Under MDUFMA, FDA was required to identify in a **Federal Register** notice those critical reprocessed SUDs whose exemption from premarket notification would be terminated and for which FDA determined that validation data, as specified under MDUFMA, was necessary in a 510(k). FDA published a list of these devices on April 30, 2003. According to the law, manufacturers of the devices whose exemptions from premarket notification were terminated were required to submit 510(k)s that included validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified in § 807.87 (21 CFR 807.87), within 15 months of publication of the notice or no longer market their devices.

In accordance with section 510(o) of the act, FDA must revise the list of devices subject to this requirement as appropriate. In the **Federal Register** of June 26, 2003 (68 FR 38071), FDA recategorized nine device types from semicritical to critical, and added nonelectric gastroenterology-urology biopsy forceps to the list of critical reprocessed SUDs whose exemption from premarket notification requirements was being terminated. In the **Federal Register** of September 29, 2005 (70 FR 56911), FDA announced that it was adding devices to the list of critical reprocessed SUDs whose 510(k) exemption is terminated and for which validation data is necessary.

By April 26, 2004, FDA was required to identify in a **Federal Register** notice those semicritical reprocessed SUDs whose exemption from premarket notification would be terminated and for which FDA determined that validation data, as specified under MDUFMA, was necessary in a 510(k). FDA published this list in the **Federal Register** of April 13, 2004 (69 FR 19433). As discussed previously in this document, manufacturers of the devices whose exemptions from premarket notification were terminated were required to submit 510(k)s that included validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements of a 510(k) identified

in § 807.87, within 15 months of publication of the notice or no longer market their devices. In accordance with section 510(o) of the act, FDA must revise the list of devices subject to this requirement as appropriate.

C. Reprocessed SUDs Already Subject to Premarket Notification Requirements

MDUFMA also required FDA to review the types of reprocessed SUDs already subject to premarket notification requirements and to identify which of these devices required the submission of validation data to ensure their substantial equivalence to predicate devices. FDA published a list of these devices in the **Federal Register** of April 30, 2003. As described previously in this document, FDA must revise the list of devices subject to this requirement as appropriate. In the **Federal Register** of September 29, 2005, FDA announced that it was adding laparoscopic and endoscopic electrosurgical accessories to this list of reprocessed SUDs already subject to premarket notification.

For devices identified on this list that had already been cleared through the 510(k) process, manufacturers were required to submit validation data regarding cleaning, sterilization, and functional performance within 9 months of publication of the list or no longer market their devices.

For devices on this list that were not yet cleared through the 510(k) process, manufacturers were required to submit 510(k)s with validation data regarding cleaning, sterilization, and functional performance, in addition to all the other required elements identified in § 807.87.

II. What Does This Direct Final Rulemaking Do?

In this final rule, FDA is:

- Amending § 807.3 to add definitions for ''single use device,'' ''reprocessed single use device (SUD)'' and ''validation data.'' The definitions of single use device and reprocessed single use device reflect the definitions of those terms in section 201(ll) of the act as amended by MDUFMA. The definition of validation data tracks the language used to describe validation data in section 510(o)(1)(A) of the act.
- Amending § 807.87 (Information required in a premarket notification submission) to reference the requirement (of section 510(o) of the act) to submit validation data for reprocessed SUDs in appropriate situations.
- Amending the classification regulations for devices for which FDA has revoked the exemption from premarket notification submission for reprocessed SUDs that require the submission of validation data. If the revocation applies only to a subset within a generic type, FDA has revised the language accordingly.
- Amending the classification regulations for devices already subject to premarket notification that FDA has designated as requiring the submission of validation data. If the requirement to submit validation data applies only to a subset of the generic type, FDA has revised the regulation accordingly.
- Making minor corrections to the classification regulations, including amending the sections for affected class II devices to update the definition of class II from requiring ''performance standards'' to requiring ''special controls'' in order to provide a reasonable assurance of the safety and effectiveness of the device. This conforms these sections to the definition of class II at section 513(a)(1)(B) of the act (21 U.S.C. 360c(a)(1)(B)), as revised by the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629).

FDA has made available previously a guidance document on the submission of validation data entitled ''Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices'' (June 1, 2004, 69 FR 30943). This guidance document may be accessed on the Internet at *http://www.fda.gov/cdrh/ode/guidance/1216.html*.

III. What are the Procedures for Issuing a Direct Final Rule?

In the **Federal Register** of November 21, 1997 (62 FR 62466), FDA announced the availability of the guidance document entitled ''Guidance for FDA and Industry: Direct Final Rule Procedures'' that described when and how FDA will employ direct final rulemaking. We believe that this rule is appropriate for direct final rulemaking because it is intended to make noncontroversial amendments and minor corrections to existing regulations. We anticipate no significant adverse comment.

Consistent with FDA's procedures on direct final rulemaking, we are publishing elsewhere in this issue of the **Federal Register** a companion proposed rule that is identical to the direct final rule. The companion proposed rule provides a procedural framework within which the rule may be finalized in the event the direct final rule is withdrawn because of any significant adverse comment. The comment period for this direct final rule runs concurrently with the comment period of the companion proposed rule. Any comments received in response to the companion proposed rule will also be considered as comments regarding this direct final rule.

If we receive any significant adverse comment, we intend to withdraw this final rule before its effective date by publication of a notice in the **Federal Register** within 30 days after the comment period ends. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without change. In determining whether an adverse comment is significant and warrants terminating a direct final rulemaking, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant adverse comment, unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

If we withdraw the direct final rule, all comments received will be considered under the companion proposed rule in developing a final rule under the usual notice-and-comment procedures under the APA (5 U.S.C. 552a *et seq.*). If we receive no significant adverse comment during the specified comment period, we intend to publish a confirmation document in the **Federal Register** within 30 days after the comment period ends.

IV. What is the Legal Authority for This Rule?

This direct final rule is authorized by sections 201, 301, 501, 502, 510, 513, 515, 519, 520, 701, 704, 801, and 903 of the act and sections 264 and 271 of the Public Health Service Act (21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264 and 271).

V. What is the Environmental Impact of This Rule?

We have determined under 21 CFR 25.30(h) and 25.34(a) that this 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.

VI. What is the Economic Impact of This Rule?

We have examined the impacts of the final 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). We believe that this direct final 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. Because this regulation only codifies in regulations existing statutory requirements, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes 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 $118 million, using the most current (2004) Implicit Price Deflator for the Gross Domestic Product. We do not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VII. How Does the Paperwork Reduction Act of 1995 Apply to This Rule?

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the direct final rule have been approved by OMB in accordance with the PRA under the regulations governing premarket notifications (21 CFR part 807, OMB control number 0910–0120).

VIII. What are the Federalism Impacts of This Rule?

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

IX. How Do You Submit Comments on This Rule?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this direct final rule. 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.

X. What Is the Reference for This Rule?

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 am. and 4 pm., Monday through Friday.

1. Spaulding, E. H., ''The Role of Chemical Disinfection in the Prevention of Nonsocomial Infections.'' Edited by P. S. Brachman and T. C. Eickof, Proceedings of International Conference on Nonsocomial Infections, 1970, American Hospital Association, Chicago, 254–274, 1971.

List of Subjects

21 CFR Part 807

Confidential business information, Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Parts 868, 870, 872, 874, 876, 878, 880, 882, and 884

Medical devices.

21 CFR Part 886

Medical devices, Opthalmic goods and services.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 807, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, and 892 are amended as follows:

PART 807—ESTABLISHMENT REGISTRATION AND DEVICE LISTING FOR MANUFACTURERS AND INITIAL IMPORTERS OF DEVICES

■ 1. The authority citation for 21 CFR part 807 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360, 360c, 360e, 360i, 360j, 371, 374, 381, 393; 42 U.S.C. 264, 271.

■ 2. Section 807.3 is amended by adding new paragraphs (t), (u), and (v) to read as follows:

§ 807.3 Definitions.

* * * * *

(t) A single use device (SUD) means a device that is intended for one use or on a single patient during a single procedure.

(u) A reprocessed SUD is an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed SUD shall result in a device that is reprocessed within the meaning of this definition.

(v) Validation data for the purposes of this part means cleaning and sterilization data, and functional performance data demonstrating that an SUD will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification.

■ 3. Section 807.87 is amended by redesignating paragraphs (h), (i), (j), (k), and (l) as paragraphs (i), (j), (k), (l), and (m), respectively, and by adding new paragraph (h) to read as follows:

§ 807.87 Information required in a premarket notification submission.

* * * * *

(h) If the device is a reprocessed SUD that FDA has identified as requiring validation data, the premarket

notification submission must include validation data as defined in § 807.3(v).

* * * * *

PART 868—ANESTHESIOLOGY DEVICES

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

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

■ 5. Section 868.5150 is amended by revising paragraph (b) to read as follows:

§ 868.5150 Anesthesia conduction needle.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an anesthetic conduction needle (with/without introducer) or a short term spinal needle and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 6. Section 868.5730 is amended by revising paragraph (b) to read as follows:

§ 868.5730 Tracheal tube.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 7. Section 868.5905 is amended by revising paragraph (b) to read as follows:

§ 868.5905 Noncontinuous ventilator (IPPB).

* * * * *

(b) *Classification.* Class II (special controls). If the device is a noncontinuous ventilator (respirator) mask that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 8. Section 868.6810 is amended by revising paragraph (b) to read as follows:

§ 868.6810 Tracheobronchial suction catheter.

* * * * *

(b) *Classification.* Class I (general controls). 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. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

PART 870—CARDIOVASCULAR DEVICES

■ 9. The authority citation for 21 CFR part 870 continues to read as follows:

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

■ 10. Section 870.1200 is amended by revising paragraph (b) to read as follows:

§ 870.1200 Diagnostic intravascular catheter.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an angiography catheter that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 11. Section 870.1220 is amended by revising paragraph (b) to read as follows:

§ 870.1220 Electrode recording catheter or electrode recording probe.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an electrode recording catheter or intracardiac mapping catheter that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 12. Section 870.1230 is amended by revising paragraph (b) to read as follows:

§ 870.1230 Fiberoptic oximeter catheter.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 13. Section 870.1280 is amended by revising paragraph (b) to read as follows:

§ 870.1280 Steerable catheter.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 14. Section 870.1290 is amended by revising paragraph (b) to read as follows:

§ 870.1290 Steerable catheter control system.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 15. Section 870.1330 is amended by revising paragraph (b) to read as follows:

§ 870.1330 Catheter guide wire.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 16. Section 870.1390 is amended by revising paragraph (b) to read as follows:

§ 870.1390 Trocar.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a cardiovascular trocar that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

17. Section 870.1650 is amended by revising paragraph (b) to read as follows:

§ 870.1650 Angiographic injector and syringe.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 18. Section 870.1670 is amended by revising paragraph (b) to read as follows:

§ 870.1670 Syringe actuator for an injector.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 19. Section 870.2700 is amended by revising paragraph (b) to read as follows:

§ 870.2700 Oximeter.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a tissue saturation oximeter or an oximeter and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include

validation data as described in § 807.3(v).

■ 20. Section 870.3535 is amended by revising paragraph (b) to read as follows:

§ 870.3535 Intra-aortic balloon and control system.

* * * * *

(b) *Classification.* Class III (premarket approval). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

* * * * *

■ 21. Section 870.4450 is amended by revising paragraph (b) to read as follows:

§ 870.4450 Vascular clamp.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 22. Section 870.4500 is amended by revising paragraph (b) to read as follows:

§ 870.4500 Cardiovascular surgical instruments.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 870.9. If the device is a noncompression heart stabilizer that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 23. Section 870.4885 is amended by revising paragraph (b) to read as follows:

§ 870.4885 External vein stripper.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 872—DENTAL DEVICES

■ 24. The authority citation for 21 CFR part 872 continues to read as follows:

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

■ 25. Section 872.3240 is amended by revising paragraph (b) to read as follows:

§ 872.3240 Dental bur.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is a dental diamond coated bur that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification submission that includes validation data as described in § 807.3(v).

■ 26. Section 872.4535 is amended by revising paragraph (b) to read as follows:

§ 872.4535 Dental diamond instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 27. Section 872.4730 is amended by revising paragraph (b) to read as follows:

§ 872.4730 Dental injecting needle.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 28. Section 872.5410 is amended by revising paragraph (b) to read as follows:

§ 872.5410 Orthodontic appliance and accessories.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is a orthodontic metal bracket that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 29. Section 872.5470 is amended by revising paragraph (b) to read as follows:

§ 872.5470 Orthodontic plastic bracket.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 30. The authority citation for 21 CFR part 874 continues to read as follows:

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

■ 31. Section 874.4140 is amended by revising paragraph (b) to read as follows:

§ 874.4140 Ear, nose, and throat bur.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. If the device is an ear, nose, and throat (ENT) high speed microdebrider or an ENT diamond coated bur and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 32. Section 874.4420 is amended by revising paragraph (b) to read as follows:

§ 874.4420 Ear, nose, and throat manual surgical instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. If the device is a laryngeal, sinus, or tracheal trocar that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 33. Section 874.4680 is amended by revising paragraph (b) to read as follows:

§ 874.4680 Bronchoscope (flexible or rigid) and accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a bronchoscope (nonrigid) biopsy forceps that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 34. The authority citation for 21 CFR part 876 continues to read as follows:

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

■ 35. Section 876.1075 is amended by revising paragraph (b) to read as follows:

§ 876.1075 Gastroenterology-urology biopsy instrument.

* * * * *

(b) *Classification.* (1) Class II (special controls). If the device is a gastroenterology-urology (G–U) biopsy needle and needle set or a biopsy instrument and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

(2) Class I (general controls) for the biopsy forceps cover and the non-electric biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. If the device is a non-electric biopsy forceps that is a reprocessed SUD as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 36. Section 876.1500 is amended by revising paragraph (b) (1) to read as follows:

§ 876.1500 Endoscope and accessories.

* * * * *

(b) *Classification.* (1) Class II (special controls). If the device is an endoscopic needle, an endoilluminator, a general and plastic surgery laparoscope, or a spring-loaded pneumoperitoneum needle and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

* * * * *

■ 37. Section 876.4300 is amended by revising paragraph (b) to read as follows:

§ 876.4300 Endoscopic electrosurgical unit and accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an active urological electrosurgical electrode, a flexible suction coagulator electrode, an electric biopsy forceps, a flexible snare, or an endoscopic (with or without accessories) electrosurgical unit that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 38. Section 876.4680 is amended by revising paragraph (b) to read as follows:

§ 876.4680 Ureteral stone dislodger.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. If the device is a flexible and basket stone dislodger that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 39. Section 876.5010 is amended by revising paragraph (b) to read as follows:

§ 876.5010 Biliary catheter and accessories.

* * * * *

(b) *Classification.* Class II (special controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. If the device is a biliary catheter that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 40. Section 876.5540 is amended in paragraph (b) (3) to read as follows:

§ 876.5540 Blood access device and accessories.

* * * * *

(b) * * *

(3) Class II (special controls) for accessories for both the implanted and the nonimplanted blood access devices not listed in paragraph (b)(4) of this section. If the device is a single needle dialysis set (coaxial flow) or fistula needle and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

* * * * *

■ 41. Section 876.5820 is amended by revising paragraph (b) (1) to read as follows:

§ 876.5820 Hemodialysis system and accessories.

* * * * *

(b) *Classification.* (1) Class II (special controls) (for hemodialysis systems and all accessories directly associated with the extracorporeal blood system and the dialysate delivery system). If the device is a single needle dialysis set with uni-directional pump that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

* * * * *

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 42. The authority citation for 21 CFR part 878 continues to read as follows:

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

■ 43. Section 878.4200 is amended by revising paragraph (b) to read as follows:

§ 878.4200 Introduction/drainage catheter and accessories.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9. If the device is a catheter needle that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 44. Section 878.4300 is amended by revising paragraph (b) to read as follows:

§ 878.4300 Implantable clip.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 45. Section 878.4400 is amended by revising paragraph (b) to read as follows:

§ 878.4400 Electrosurgical cutting and coagulation device and accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an endoscopic or laparoscopic electrosurgical accessory that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 46. Section 878.4750 is amended by revising paragraph (b) to read as follows:

§ 878.4750 Implantable staple.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 47. Section 878.4800 is amended by revising paragraph (b) to read as follows:

§ 878.4800 Manual surgical instrument for general use.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 878.9. If the device is a percutaneous biopsy device, a gastroenterology-urology needle, a cardiovascular biopsy needle, or an aspiration and injection needle and it is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 48. The authority citation for 21 CFR part 880 continues to read as follows:

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

■ 49. Section 880.5570 is amended by revising paragraph (b) to read as follows:

§ 880.5570 Hypodermic single lumen needle.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 50. Section 880.5860 is amended by revising paragraph (b) to read as follows:

§ 880.5860 Piston syringe.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 882—NEUROLOGICAL DEVICES

■ 51. The authority citation for 21 CFR part 882 continues to read as follows:

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

■ 52. Section 882.4190 is amended by revising paragraph (b) to read as follows:

§ 882.4190 Clip forming/cutting instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 53. Section 882.4300 is amended by revising paragraph (b) to read as follows:

§ 882.4300 Manual cranial drills, burrs, trephines, and accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 54. Section 882.4305 is amended by revising paragraph (b) to read as follows:

§ 882.4305 Powered compound cranial drills, burrs, trephines, and their accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 55. Section 882.4310 is amended by revising paragraph (b) to read as follows:

§ 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 56. The authority citation for 21 CFR part 884 continues to read as follows:

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

■ 57. Section 884.1720 is amended by revising paragraph (b)(1) to read as follows:

§ 884.1720 Gynecologic laparoscope and accessories.

* * * * *

(b) (1) *Classification.* Class II (special controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

* * * * *

■ 58. Section 884.1730 is amended by revising paragraph (b)(2) to read as follows:

§ 884.1730 Laparoscopic insufflator.

* * * * *

(b) * * *

(2) Class I for tubing and tubing/filter kits which include accessory instruments that are not used to effect intra-abdominal insufflation (pneumoperitoneum). The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9. If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 59. Section 884.4530 is amended by revising paragraph (b)(2) to read as follows:

§ 884.4530 Obstetric-gynecologic specialized manual instrument.

* * * * *

(b) * * *

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, intrauterine device (IUD) remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 884.9. If the device is a

gynecological biopsy forceps that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 60. Section 884.6100 is amended by revising paragraph (b) to read as follows:

§ 884.6100 Assisted reproduction needles.

* * * * *

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

PART 886—OPTHALMIC DEVICES

■ 61. The authority citation for 21 CFR part 886 continues to read as follows:

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

■ 62. Section 886.4350 is amended by revising paragraph (b) to read as follows:

§ 886.4350 Manual ophthalmic surgical instrument .

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. If the device is an ophthalmic knife that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, the exemption from premarket notification does not apply and the manufacturer must submit a premarket notification that includes validation data as described in § 807.3(v).

■ 63. Section 886.4370 is amended by revising paragraph (b) to read as follows:

§ 886.4370 Keratome.

* * * * *

(b) *Classification.* Class I (general controls). If the device is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

■ 64. Section 886.4670 is amended by revising paragraph (b) to read as follows:

§ 886.4670 Phacofragmentation system.

* * * * *

(b) *Classification.* Class II (special controls). If the device is a phacoemulsification needle that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

PART 892—RADIOLOGY DEVICES

■ 65. The authority citation for 21 CFR part 892 continues to read as follows:

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

■ 66. Section 892.5730 is amended by revising paragraph (b) to read as follows:

§ 892.5730 Radionuclide brachytherapy source.

* * * * *

(b) *Classification.* Class II (special controls). If the device is an isotope needle that is a reprocessed single use device (SUD) as defined in § 807.3(u) of this chapter, a premarket notification submission for the device must include validation data as described in § 807.3(v).

Dated: September 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–8166 Filed 9–22–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 06–022]

RIN 1625–AA00

Safety Zone; BART Transbay Tube Seismic Upgrade, San Francisco, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a moving temporary safety zone in the navigable waters of San Francisco Bay, California during vibro penetration testing for a seismic upgrade of the Bay Area Rapid Transit (BART) Transbay tube. The testing will require placement of a barge at test sites along the BART Transbay tube. The safety zone will surround the barge and move with the barge as it conducts the tests at seven sites along the BART Transbay tube. This safety zone is necessary to protect persons and vessels from hazards, injury, and damage associated with the vibro penetration testing. Unauthorized persons or vessels are prohibited from entering into, transiting through, or remaining in the safety zone without permission of the Captain of the Port or his designated representative.

DATES: This rule is effective from September 25, 2006 through December 31, 2006.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket COTP San Francisco Bay 06–022 and are available for inspection or copying at the Waterways Safety Branch of Sector San Francisco, Yerba Buena Island, Bldg. 278, San Francisco, California, 94130, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Ensign Erin Bastick, U.S. Coast Guard Sector San Francisco, at (415) 556–2950 or Sector San Francisco 24 hour Command Center at (415) 399–3547.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The dates for the vibro penetration testing along the Transbay tube were not finalized and presented to the Coast Guard in time to draft and publish an NPRM. As such, the testing would commence before the rulemaking process could be completed. Any delay in implementing this rule is contrary to the public interest since immediate action is necessary in order to protect the maritime public from the hazards associated with the vibro penetration testing.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The dates for the vibro penetration testing along the Transbay tube were not finalized and presented to the Coast Guard in time to publish this rule 30 days prior to its effective date. As such, the testing would commence before the rulemaking process could be completed. Delay in the effective date of this rule would expose the mariners and waterways users to undue hazards associated with the vibro penetration testing.

Background and Purpose

Bay Area Rapid Transit has contracted Hayward Baker, Soletanche, Traylor, A Joint Venture, to conduct BART marine demonstration tests in support of their earthquake safety efforts. They will be