

Windsor Locks, CT, Bradley Intl, COPTER ILS 058, Amdt 2A, CANCELLED

Yap Island, FM, Yap Intl, NDB RWY 7, Amdt 2

Yap Island, FM, Yap Intl, NDB/DME RWY 7, Amdt 2

Yap Island, FM, Yap Intl, NDB/RWY 25, Orig

Yap Island, FM, Yap Intl, NDB/DME RWY 25, Orig

Brunswick, GA, Malcom McKinnon, VOR RWY 4, Amdt 16

Brunswick, GA, Malcom McKinnon, NDB RWY 4, Amdt 1

Brunswick, GA, Malcom McKinnon, NDB RWY 22, Amdt 1

Hinesville, GA, Liberty County, NDB-A, Admt 3

Hinesville, GA, Liberty County, RNAV (GPS) RWY 32, Orig

Hinesville, GA, Liberty County, GPS RWY 32, Orig, CANCELLED

Savannah, GA, Savannah/Hilton Head Intl, VOR OR TACAN OR GPS RWY 27, Amdt 15D, CANCELLED

Savannah, GA, Savannah/Hilton Head Intl, ILS RWY 9, Amdt 26

Savannah, GA, Savannah/Hilton Head Intl, ILS RWY 36, Amdt 7

Savannah, GA, Savannah/Hilton Head Intl, NDB RWY 9, Amdt 22

Savannah, GA, Savannah/Hilton Head Intl, MLS RWY 27, Amdt 1

Statesboro, GA, Statesboro-Bulloch County, ILS RWY 32, Amdt 1

Statesboro, GA, Statesboro-Bulloch County, NDB RWY 32, Amdt 6

Chicago/Aurora, IL, Aurora Muni, VOR/DME RNAV RWY 27, Amdt 1

Chicago/Aurora, IL, Aurora Muni, ILS RWY 9, Amdt 2

Chicago/Aurora, IL, Aurora Muni, RNAV (GPS) RWY 9, Orig

Chicago/Aurora, IL, Aurora Muni, RNAV (GPS) RWY 27, Orig

Moundridge, KS, Moundridge Muni, RNAV (GPS) RWY 17, Orig

Moundridge, KS, Moundridge Muni, RNAV (GPS) RWY 35, Orig

Bastrop, LA, Morehouse Memorial, VOR/DME-A, Amdt 9

Bastrop, LA, Morehouse Memorial, NDB RWY 34, Amdt 6

Bastrop, LA, Morehouse Memorial, RNAV (GPS) RWY 16, Orig

Bastrop, LA, Morehouse Memorial, GPS RWY 16, Orig, CANCELLED

Baudette, MN, Baudette Intl, RNAV (GPS) RWY 12, Orig-A

Baudette, MN, Baudette Intl, RNAV (GPS) RWY 30, Orig-A

Pedricktown, NJ, Spitfire Aerodrome, RNAV (GPS) RWY 7, Orig

Pedricktown, NJ, Spitfire Aerodrome, RNAV (GPS) RWY 25, Orig

Durant, OK, Eaker Field, VOR/DME RWY 17, Orig

Durant, OK, Eaker Field, VOR/DME RWY 35, Amdt 6

Durant, OK, Eaker Field, NDB RWY 35, Orig

Durant, OK, Eaker Field, RNAV (GPS) RWY 17, Orig

Durant, OK, Eaker Field, RNAV (GPS) RWY 35, Orig

Durant, OK, Eaker Field, GPS RWY 35, Orig-A, CANCELLED

Babelthuap Island, PS, Babelthuap/Koror, RNAV (GPS) RWY 9, Orig

Babelthuap Island, PS, Babelthuap/Koror, RNAV (GPS) RWY 27, Orig

Babelthuap Island, PW, Babelthuap/Koror, GPS RWY 9, AMDT 1B (CANCELLED)

Babelthuap Island, PW, Babelthuap/Koror, GPS RWY 27, AMDT 1B (CANCELLED)

Providence, RI, Theodore Francis Green State, VOR RWY 34, Amdt 4C

Providence, RI, Theodore Francis Green State, VOR/DME RWY 23L, Amdt 6E

Providence, RI, Theodore Francis Green State, ILS RWY 5R, Amdt 18

Providence, RI, Theodore Francis Green State, ILS RWY 23L, Amdt 5

Providence, RI, Theodore Francis Green State, ILS RWY 34, Amdt 10

Providence, RI, Theodore Francis Green State, RNAV (GPS) Y RWY 5R, Orig

Providence, RI, Theodore Francis Green State, RNAV (GPS) Z RWY 5R, Orig

Providence, RI, Theodore Francis Green State, RNAV (GPS) RWY 16, Orig

Providence, RI, Theodore Francis Green State, RNAV (GPS) RWY 23L, Orig

Providence, RI, Theodore Francis Green State, RNAV (GPS) RWY 34, Orig

Providence, RI, Theodore Francis Green State, GPS RWY 16, Orig-B, CANCELLED

Beaufort, SC, Beaufort County, RNAV (GPS) RWY 7, Orig

Beaufort, SC, Beaufort County, RNAV (GPS) RWY 25, Orig.

Beaufort, SC, Beaufort County, GPS RWY 24, Orig-A CANCELLED

Hilton Head Island, SC, Hilton Head, LOC/DME RWY 21, Amdt 3

Houston, TX, Houston-Southwest, RNAV (GPS) RWY 9, Amdt 1

Houston, TX, Houston-Southwest, VOR/DME RNAV RWY 9, Amdt 2, CANCELLED

Houston, TX, Houston-Southwest, VOR/DME RNAV RWY 27, Amdt 3, CANCELLED

Ozona, TX, Ozona Muni, RNAV (GPS) RWY 16, Orig

Ozona, TX, Ozona Muni, GPS RWY, 16, CANCELLED

Snyder, TX, Winston Field, NDB RWY 35, Amit 2

Snyder, TX, Winston Field, RNAV (GPS) RWY 35, Orig

Yoakum, TX, Yoakum, Muni, NDB RWY 31, Amdt 3

Yoakum, TX, Yoakum, Muni, RNAV (GPS) RWY 31, Orig

Salt Lake, City, UT, Salt Lake City Muni 2, RNAV (GPS) RWY 34, Amdt 1

Wallops Island, VA, Wallops Flight Facility, VOR OR TACAN RWY 17, Amdt 6B

Wallops Island, VA, Wallops Flight Facility, RNAV (GPS) RWY 4, Orig

Wallops Island, VA, Wallops Flight Facility, RNAV (GPS) RWY 10, Orig

Wallops Island, VA, Wallops Flight Facility, RNAV (GPS) RWY 17, Orig

Wallops Island, VA, Wallops Flight Facility, RNAV (GPS) RWY 22, Orig

Wallops Island, VA, Wallops Flight Facility, RNAV (GPS) RWY 28, Orig

Parkersburg, WV, Wood County Airport-Gill Robb Wilson Field, ILS RWY 3, Amdt 12

*Effective August 7, 2003*

Clintonville, WI, Clintonville Muni, NDB RWY 32, Amdt 7

*Effective September 4, 2003*

Sioux Falls, SD, Joe Foss Field, VOR OR TACAN RWY 15, Amdt 21

Sioux Falls, SD, Joe Foss Field, NDB RWY 3, Amdt 24A

Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 3, Orig

Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 9, Orig

Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 15, Orig

Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 21, Orig

Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 27 Orig

Sioux Falls, SD, Joe Foss Field, RNAV (GPS) RWY 33, Orig

Sioux Falls, SD, Joe Foss Field, GPS RWY 33, Orig, CANCELLED

[FR Doc. 03-13542 Filed 5-30-03; 8:45 am]

BILLING CODE 4910-13-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 888

[Docket No. 01N-0411]

#### Orthopedic Devices; Classification for the Resorbable Calcium Salt Bone Void Filler Device

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the resorbable calcium salt bone void filler device intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure into class II (special controls). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a class II special controls guidance entitled "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA." This action is being undertaken based on new information submitted in a classification proposal from Wright Medical Technology under the Federal Food, Drug, and Cosmetic Act as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Food and Drug Administration Modernization Act of 1997.

**DATES:** This rule is effective July 2, 2003

**FOR FURTHER INFORMATION CONTACT:** Nadine Y. Sloan, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200

Corporate Blvd., Rockville, MD 20850, 301-594-1296.

#### SUPPLEMENTARY INFORMATION:

### I. Background

In the **Federal Register** of February 7, 2002 (67 FR 5753), FDA issued a proposed rule to classify the resorbable calcium salt bone void filler device into class II based on new information regarding this device and on the recommendation of the Orthopedic and Rehabilitation Devices Panel. FDA identified the draft guidance document entitled "Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Draft Guidance for Industry and FDA" as the proposed special control capable of providing reasonable assurance of the safety and effectiveness of the device. The device is intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or surgery and are not intrinsic to the stability of the bony structure. FDA invited interested persons to comment on the proposed rule by May 8, 2002. FDA received two comments, both supporting the proposed classification. One of the two comments also requested minor changes to the class II special controls guidance document.

### II. Analysis of Comments and FDA's Response

One comment expressed concern over a perceived intent to apply the guidance to demineralized bone matrix (DBM) products. FDA acknowledges that there was a misunderstanding about whether the proposed rule applied to DBM products that have the same intended use as the resorbable calcium salt bone void filler device and that were recently determined to be medical devices. The proposed rule was intended to be specific to the resorbable calcium salt bone void filler device, including resorbable calcium salt bone void fillers that may contain some biologically sourced additives, including DBM. The proposed rule was not intended to apply to DBM products, i.e., products that contain DBM without any calcium salt or that are composed primarily of DBM. For clarity, FDA has deleted reference to all biologically sourced materials included in the proposed rule and draft class II special controls guidance and will address devices made of these other materials in the future.

### III. FDA's Conclusion

Based on a review of the available information in the preamble to the proposed rule and placed on file in FDA's Dockets Management Branch, FDA concludes that special controls, in

conjunction with general controls, provide reasonable assurance of the device safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the class II special controls guidance document. The class II special controls guidance document was revised to reflect consideration of the comments received. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a resorbable calcium salt bone void filler device will need to address the issues covered in the class II special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA is now codifying the classification and the class II special control guidance document for the resorbable calcium salt bone void filler device by adding § 888.3045. For the convenience of the reader, FDA is also adding § 888.1(e) to inform the reader where to find guidance documents referenced in 21 CFR part 888.

### IV. Environmental Impact

The agency has determined under 21 CFR 25.34(b) 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.

### V. Analysis of Impacts

FDA has 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). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under 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. These devices are already subject to general controls, such as premarket notification. The class II special controls guidance document will not substantially change the way in which these devices are regulated. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

### VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has 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, the agency has 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.

### VII. Paperwork Reduction Act of 1995

This final rule does not contain information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

#### List of Subjects in 21 CFR Part 888

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 888 is amended as follows:

#### PART 888—ORTHOPEDIC DEVICES

■ 1. The authority citation for 21 CFR part 888 continues to read as follows:

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

■ 2. Section 888.3045 is added to subpart D to read as follows:

#### § 888.3045 Resorbable calcium salt bone void filler device.

(a) *Identification.* A resorbable calcium salt bone void filler device is a resorbable implant intended to fill bony voids or gaps of the extremities, spine, and pelvis that are caused by trauma or

surgery and are not intrinsic to the stability of the bony structure.

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA." See § 888.1(e) of this chapter for the availability of this guidance.

Dated: April 9, 2003.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

[FR Doc. 03-13592 Filed 5-30-03; 8:45 am]

BILLING CODE 4160-01-S

## DEPARTMENT OF LABOR

### Occupational Safety and Health Administration

#### 29 CFR Part 1910

#### Powered Industrial Trucks

**AGENCY:** Occupational Safety and Health Administration (OSHA), Department of Labor.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** This technical amendment deletes a Powered Industrial Trucks Standard covering the use of powered industrial trucks to lift personnel. It is being deleted because it was invalidly promulgated from a non-mandatory provision of a national consensus standard.

**DATES:** This final rule becomes effective on July 2, 2003.

**FOR FURTHER INFORMATION CONTACT:** For general information and press contact Ms. Bonnie Friedman, Director, Office of Communications, OSHA, U.S. Department of Labor, Rm. N3637, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693-1999, Fax (202) 693-1634. For technical information contact: David Wallis, Office of Engineering Safety, Room N3609, telephone (202) 693-2064, or Patrick Kapust, Office of General Industry Enforcement, Room N3107, telephone (202) 693-1854 at the above address.

**SUPPLEMENTARY INFORMATION:** In section 6(a) of the Occupational Safety and Health Act of 1970, 84 Stat. 1593; 29 U.S.C. 655(a), Congress authorized OSHA to adopt national consensus standards and established Federal Standards without prior notice and public participation. On May 29, 1971, at 36 FR 10466, OSHA published a final

rule in the **Federal Register** adopting national consensus standards and established Federal standards as OSHA's initial occupational safety and health standards for general industry.

The preamble to that final rule contained the following statement:

I do hereby designate as national consensus standards those standards in Part 1910 which are standards adopted and promulgated by either the American National Standards Institute (ANSI) or the National Fire Protection Association (NFPA). The national consensus standards contain *only mandatory provisions* of the standards promulgated by those two organizations. *The standards of ANSI and NFPA may also contain advisory provisions and recommendations the adoption of which by employers is encouraged, but they are not adopted in Part 1910.* (36 FR 10466) (emphasis added).

Thus, the standards adopted on May 29, 1971, were intended to include only the mandatory provisions of the relevant ANSI and NFPA standards.

The American National Standard for Powered Industrial Trucks, ANSI B56.1-1969, was one of the national consensus standards that the Agency adopted under section 6(a). That ANSI standard was the source standard for 29 CFR 1910.178(e) through (p), the relevant paragraphs of OSHA's Powered Industrial Trucks Standard.

Paragraph (m)(12) of § 1910.178, as it was published in May 1971 and as it still appears today, reads as follows:

Whenever a truck is equipped with vertical only, or vertical and horizontal controls elevatable with the lifting carriage or forks for lifting personnel, the following additional precautions *shall be taken* for the protection of personnel being elevated.

(i) Use of a safety platform firmly secured to the lifting carriage and/or forks.

(ii) Means *shall be provided* whereby personnel on the platform can shut off power to the truck.

(iii) Such protection from falling objects as indicated necessary by the operating conditions *shall be provided*. [Emphasis added.]

The requirement thus appears as a mandatory provision of OSHA's Powered Industrial Truck Standard.

The corresponding provision in the base standard, ANSI B56.1-1969, was contained in section 604L, which read as follows:

Whenever a truck is equipped with vertical only, or vertical and horizontal travel controls elevatable with the lifting carriage or forks for lifting personnel, the following additional precautions *should be taken* for the protection of personnel being elevated.

(a) Use of a safety platform firmly secured to the lifting carriage and/or forks.

(b) Provide means whereby personnel on the platform can shut off power to the truck.

(c) Provide such protection from falling objects as indicated necessary by the operating conditions. [Emphasis added.]

Consequently, OSHA revised the language of this subparagraph in the ANSI standard and, in doing so, made it mandatory instead. If a provision was not mandatory ("should"), in the source consensus standard, the corresponding OSHA provision that was invalidly adopted as ("shall") mandatory is not enforceable [see *Usery v. Kennecott Copper Corporation*, 577 F.2d 1113, 1117 (10th Cir. 1977)]. Consequently, § 1910.178(m)(12) is unenforceable by OSHA.

Because it is unenforceable, OSHA is removing that provision, 29 CFR 1910.178(m)(12), from the Powered Industrial Trucks Standard. Note that OSHA is removing all of paragraph (m)(12), including its subordinate paragraphs (m)(12)(i) through (m)(12)(iii).

This action does not indicate that the underlying hazard addressed by these provisions is not serious. Indeed, if proper equipment, procedures and training are not provided, the lifting of personnel with powered industrial trucks poses hazards likely to cause death or serious injury to employees. As noted in OSHA's 1998 amendment to the Powered Industrial Trucks Standard, a significant percentage (4 to 14% depending on the study) of the 100 deaths and 95,000 injuries per year that involve powered industrial trucks, result from falls from personnel lifting. (See 63 FR 66238, December 1, 1998). The American Society of Mechanical Engineers' (ASME) current standard for powered industrial trucks (ASME B56.1-2000) addresses these hazards. For example, operator-up highlift trucks (order pickers, etc.) are addressed by paragraphs 4.17.1, 4.17.2 and 7.36. Trucks with work platforms which do not fit that category are covered by paragraphs 4.17.2, 4.17.3 and 7.36.3.

Under the Voluntary Consensus Standards Project (RIN 1218-AC08), the Agency has asked various consensus standards organizations to review their standards, compare the latest versions of these standards to the ones currently adopted by OSHA, and to determine which ones are most important for OSHA to update. The organizations have provided considerable information on priorities and other related issues. OSHA is in the process of evaluating the information it has received from the consensus standards organizations and is now considering the possibility of initiating rulemaking to revise and update the Powered Industrial Truck Standard.