

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870 and 882

[Docket No. 2003N-0567]

Cardiovascular and Neurological Devices; Reclassification of Two Embolization Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to reclassify two embolization device types from class III (premarket approval) into class II (special controls). The agency is also changing the names and revising the identifications of these devices. The vascular embolization device (previously the arterial embolization device) is intended to control hemorrhaging due to aneurysms, certain types of tumors, and arteriovenous malformations. The neurovascular embolization device (previously the artificial embolization device) is intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. FDA is reclassifying these devices on its own initiative on the basis of new information. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990, the Food and Drug Administration Modernization Act of 1997, and the Medical Device User Fee and Modernization Act of 2002.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for these devices.

DATES: This rule is effective [*insert date 30 days after date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Peter L. Hudson, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-3090.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et seq.*) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as “preamendments devices.” FDA classifies these devices after the agency initiates the following procedures: (1) Receives a recommendation from a device classification panel (an FDA advisory committee); (2) publishes the panel’s recommendation for comment, along with a proposed regulation classifying the device; and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures. FDA refers to devices that were not in commercial distribution before May 28, 1976, as “postamendments devices.”

These devices are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. The devices remain in class III and require premarket approval, unless FDA initiates the following procedures: (1) Reclassifies the device into class I or II; (2) issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act; or (3) issues, under section 513(i) of the act, an order finding the device substantially equivalent to a predicate device that does not require premarket approval. As described in section 510(k) of the act (21 U.S.C. 360(k)) and under part 807 of the regulations (21 CFR part 807), FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures. Through premarket notification procedures, a person may, without submission of a premarket approval application (PMA), market a preamendments device that has been classified into class III until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(e) of the act addresses the reclassification of classified devices. This section provides that FDA may, by rulemaking, reclassify a device based on “new information.” Under section 513(e) of the act, FDA can initiate reclassification or an interested person can petition FDA to reclassify a preamendments device. The term “new information,” as used in section 513(e) of the act, includes information developed after the date of the device’s original classification. This information could include a reevaluation of the original data or information from the time of the device’s original classification that was not presented, available, or developed at that time. (See, e.g., *Holland Rantos v. United States Department of Health, Education, and Welfare*, 587 F.2d 1173,

1174 n.1 (D.C. Cir. 1978); *Upjohn v. Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell v. Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously used by FDA is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell v. Goddard*, supra, 366 F.2d at 181; *Ethicon, Inc. v. FDA*, 762 F.Supp. 382, 389–91 (D.D.C. 1991)), or in light of changes in “medical science.” (See *Upjohn v. Finch*, supra, 422 F.2d at 951.) Whether data before FDA are past or new data, the “new information” to support reclassification under section 513(e) of the act must be “valid scientific evidence,” as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). (See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc. v. FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985).) FDA relies upon “valid scientific evidence” in the classification process to determine the level of regulation for devices. When reclassifying a device, FDA can only consider valid scientific evidence that is publicly available. Publicly available information excludes trade secret and confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).))

II. Regulatory History of the Devices

In the **Federal Register** of February 25, 2004 (69 FR 8600), FDA issued a proposed rule to change the names, revise the identifications, and reclassify the two devices from class III (premarket approval) into class II (special controls). FDA identified the draft guidance document entitled “Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices” as the proposed special control capable of providing of providing reasonable assurance of the safety and effectiveness for these

devices. The vascular embolization device (previously the arterial embolization device) is intended to control hemorrhaging due to aneurysms, certain types of tumors, and arteriovenous malformations. The neurovascular embolization device (previously the artificial embolization device) is intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. FDA invited interested persons to comment on the proposed rule by May 25, 2004. FDA received one comment. The comment was supportive of the proposed reclassification but made suggestions on the guidance document's content. FDA considered the suggestions and made appropriate revisions to the guidance document.

III. Conclusion

Based on the information discussed in the preamble to the proposed rule, FDA concludes that special controls, in conjunction with general controls, will provide reasonable assurance of the safety and effectiveness for these devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document entitled "Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices" as the guidance document that will serve as the special control for these devices. FDA believes that this special controls guidance document in addition to the general controls will provide reasonable assurance of the safety and effectiveness of these devices. Following the effective date of this rule, any firm submitting a 510(k) submission for these embolization devices will need to address the issues covered in the class II special controls guidance document. However, the firm need only show that its device meets the recommendations of the class II special controls guidance document or in some other way provides equivalent assurances of safety and effectiveness.

In addition to reclassifying these devices from class III into class II, FDA has revised the name and identification of 21 CFR parts 870.330 and 882.5950. FDA believes that renaming the arterial embolization device as the “vascular embolization device” and the artificial embolization device as the “neurovascular embolization device” more accurately reflect the intended uses of these devices.

Section 870.1(e) (21 CFR 870.1(e)), which was included in the proposed rule, was previously added by a final rule published in the **Federal Register** of October 28, 2003 (68 FR 61342). Section 882.1(e) (21 CFR 882.1(e)), which was included in the proposed rule, was previously added by a final rule published in the **Federal Register** of December 18, 2003 (68 FR 70435).

IV. Environmental Impact

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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et. seq.*). 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 not a significant regulatory action 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. Reclassification of these devices from class III into class II will relieve all manufacturers of the devices of the cost of eventually complying with the premarket approval requirements in section 515 of the act. Because reclassification will therefore reduce the regulatory costs associated with these devices and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that this 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, 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 \$110 million. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

VI. Federalism

FDA has analyzed the 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, FDA 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 Parts 870 and 882

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 870 and 882 are amended as follows:

PART 870—CARDIOVASCULAR DEVICES

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

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

■ 2. Section 870.3300 is revised to read as follows:

§ 870.3300 Vascular embolization device.

(a) *Identification.* A vascular embolization device is an intravascular implant intended to control hemorrhaging due to aneurysms, certain types of tumors (e.g., nephroma, hepatoma, uterine fibroids), and arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in neurovascular applications are also not included in this classification, see § 882.5950 of this chapter.

(b) *Classification.* Class II (special controls.) The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices.” For availability of this guidance document, see § 870.1(e).

PART 882—NEUROLOGICAL DEVICES

- 3. The authority citation for 21 CFR part 882 continues to read as follows:

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

- 4. Section 882.5950 is revised to read as follows:

§ 882.5950 Neurovascular embolization device.

(a) *Identification.* A neurovascular embolization device is an intravascular implant intended to permanently occlude blood flow to cerebral aneurysms and cerebral arteriovenous malformations. This does not include cyanoacrylates and other embolic agents, which act by polymerization or precipitation. Embolization devices used in other vascular applications are also not included in this classification, see § 870.3300.

(b) *Classification.* Class II (special controls.) The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Vascular and Neurovascular Embolization Devices.” For availability of this guidance document, see § 882.1(e).

Dated: December 15, 2004.

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[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S