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AMDR
Association of Medical Device Reprocessors

April 30, 2007

BY HAND DELIVERY

U.S. Food and Drug Administration
Dockets Management Branch
Room 1-23
12420 Parklawn Drive
Rockville, Maryland 20857

CITIZEN PETITION

The Association of Medical Device Reprocessors (AMDR) respectfully submits this petition under Section 515 of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 10.30. AMDR is a trade association representing the legal and regulatory interests of third-party reprocessors of medical devices labeled for "single use." The purpose of this petition is to request that the Commissioner of Food and Drugs (the Commissioner) take action to subject certain cardiac surgery devices to premarket notification ("510(k)") requirements.

A. Action Requested

AMDR requests that FDA amend 21 C.F.R. § 870.4500, to specify that all noncompression heart positioners or stabilizers are not exempt from premarket notification procedures in subpart E of Part 807. Currently, reprocessed heart positions are subject to these premarket notification procedures while "original" (*i.e.*, unreprocessed) noncompression heart positioning devices are not. AMDR believes that the there is no statutory basis for the Commissioner to continue to allow "original" noncompression heart positioning devices to be marketed without the benefit of FDA review of a premarket notification. Accordingly, AMDR requests that the Commissioner re-evaluate the appropriateness of continuing the premarket notification exemption for original noncompression heart stabilizers and require premarket notification submissions for these devices.

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B. Statement of Grounds

Noncompression heart stabilizers are intended to move, lift, and position the heart while maintaining hemodynamic stability during cardiovascular surgery.[1] They are classified as Class I devices. Previously, heart stabilizers, whether reprocessed or original, were exempt from premarket notification requirements. On September 29, 2005, FDA announced that, in response to a request received from the original equipment industry, it had determined that reprocessed noncompression heart stabilizers should be subject to premarket notifications requirements because of the risk of cross contamination and deterioration of the mechanical properties of the device.[2] Currently, therefore, reprocessed heart stabilizers are subject to the premarket notification requirements, while original unreprocessed heart stabilizers are not.

AMDR does not believe that reprocessed heart stabilizers[3] should be subject to premarket notification requirements while heart stabilizers in general are not. AMDR therefore urges that FDA require such submissions for all noncompression heart stabilizers (*i.e.*, original and reprocessed).

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1 70 Fed. Reg. at 56912.

2 70 Fed. Reg. 56911.

3 The agency's decision with respect to reprocessed heart stabilizers was based on its belief that reprocessed noncompression heart stabilizers pose the potential for a "high risk" of infection or inadequate performance when reprocessed. 70 Fed. Reg. at 56912. Specifically, the agency said that noncompression heart stabilizers include narrow tubing, interlocking parts and small crevices that could impede the cleaning process. Moreover, FDA explained that noncompression heart stabilizers contain materials, coatings, or components that may be damaged or altered by reprocessing. AMDR notes that these assertions were not supported by any scientific data. On the contrary, AMDR members have validated processes demonstrating cleanliness, sterility and functionality of these devices. It is no more difficult for a reprocessor to ensure that these surfaces are clean and sterile than it is for an OEM to ensure that the surfaces contain no manufacturing residue. FDA's Quality System Regulation (QSR) requires both reprocessors and OEMs to conduct process validation, and AMDR's members have validated all of their cleaning and sterilization processes.

The exemption from the premarket notification requirement was originally issued in 1989,[4] pursuant to section 510(d(2)(A) of the FDCA.[5] At that time, the classification regulation stated, "The devices are exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter." The exemption was revised on July 25, 2001, to conform the exemption to section 513(l) of the Act,[6] which had been added to the Act by the Food and Drug Administration Modernization Act of 1997 (FDAMA). Pub. L. 105-115. It now reads, "The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9." It does not appear that there was in 2001 any re-evaluation of the appropriateness of the exemption for all devices subject to that classification regulation. Rather, FDA simply declared that in its proposed rule, it had "noted" that "for individual device classification sections that had been codified *previously* as exempt from premarket notification requirements, it would add the same subject-to-limitations language in the future."[7] The July, 2001 final rule simply "add[ed] that language."[8]

Section 513(l) of the FDCA states that a premarket notification submission is not required for a Class I device.[9] However, it goes on to exclude from the premarket notification exemption any device "that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury."

AMDR does not believe that original noncompression heart stabilizers meet the criteria for exemption from the premarket notification requirements. These devices are of substantial importance in preventing impairment of human health, in that they are used during open heart surgery to stabilize and properly position the heart so that the surgeon can access and complete a bypass of the patient's blocked arteries.

Furthermore, the devices clearly present a potential unreasonable risk of illness or injury. Since January 2001, there have been 73 adverse events reported to FDA involving devices with the product code "MWS" (device, stabilizer, heart). All 73 reports relate to devices manufactured by

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4 54 Fed. Reg. 25042 (June 12, 1989).

5 21 U.S.C. § 360(d)(2)(A).

6 21 U.S.C. § 360(l).

7 66 Fed. Reg. at 38786 (emphasis added).

8 *Id.*

9 21 U.S.C. § 360c.

major original equipment manufacturers (OEMs); at the time of this wring, there are no reports in FDA's MAUDE database of adverse events associated with reprocessed heart positioning devices.

These reported incidents include multiple incidents in which pieces of the stabilizer have broken off the device and fallen into the chest cavity. Many of the incidents reportedly caused injury to patients. For example, in one report, the user facility reported that "during *several* off pump procedures, the last two pods on both feet of the stabilizer caused a 'cut or rip' in the heart."[10] In another incident (also involving a failure of a stabilizer foot), the user facility apparently reported that the device had "rubbed a hole in the myocardium" which required suturing.[11] In another surgical incident, a suture "was caught on top of serrated edges of swivel mount of the vacuum stabilizer resulting in the needle driver to lift up and causing a tear on the lima."[12] All of these incidents support AMDR's position that the devices are of substantial importance in preventing impairment of human health, and presents a potential unreasonable risk of illness or injury, and therefore do not meet the statutory criteria for exemption from premarket notification provisions.

Indeed, even applying the criteria that were originally used, prior to FDAMA, to exempt certain Class I devices from premarket notification provisions, noncompression heart stabilizing devices used in cardiac surgery are not appropriate for exemption. In the preamble to the 1989 final rule exempting certain medical devices, including nonspecific cardiovascular surgical instruments from the premarket notification requirements, FDA explained that exemptions would only be granted if two criteria had been met. First, it was necessary that the device not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials. Second, it was necessary that (a) characteristics of the device necessary for its safe and effective performance were well established; (b) anticipated changes in the device

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[10] *See* FDA's MAUDE database, reporting a problem on June 7, 2004, with a Guidant Acrobat Stabilizer, model number HS-1045. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=529562.

[11] *See* FDA's MAUDE database, reporting a problem on January 21, 2004, with a Guidant Acrobat Stabilizer, model number OM-9000S. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=507867.

[12] *See* FDA's MAUDE database, reporting a problem on November 19, 2003, with a Guidant Acrobat Stabilizer, model number OM-9000S. Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=501717.

that are of the type that could affect safety and effectiveness would (i) be readily detectable by users by visual examination or other means, such as routine testing, e.g., testing of a clinical laboratory reagent with positive and negative controls, before causing harm; or (ii) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (c) any changes in the device would not be likely to result in a change in the device's classification.

Although these criteria may be satisfied for many of the devices that are covered by this classification regulation, such as forceps and scissors, AMDR believes that the characteristics of noncompression heart stabilizers that are necessary for its safe and effective performance are not so well established as to justify exemption from the premarket notification requirements.

AMDR also believes that changes in these devices since 1989, when their predecessor devices were exempted from premarket notification requirements, have "materially increased the risk of injury" associated with the use of these devices during surgery. Specifically, AMDR understands that the noncompression heart stabilizers of today have changed substantially from the heart positioning devices that existed 18 years ago. Today's devices materially increase the risk of injury, in comparison to their predecessors, because the failure of modern noncompression heart stabilizers could cause the heart to slip or fall back into the chest cavity during a beating-heart surgical procedure, potentially causing damage to the organ. Accordingly, the devices no longer meet the second of the two criteria that FDA set forth as necessary for exemption, in that changes in the device, which are "of the type that could affect safety and effectiveness . . . materially increase the risk of injury, incorrect diagnosis, or ineffective treatment."

In short, AMDR submits that, in light of the way these devices function and their intended use, it is not appropriate for FDA to treat them as exempt from premarket notification requirements, equivalent to the "forceps, retractors, and scissors" mentioned in the classification regulation. We urge the Commissioner to re-evaluate the appropriateness of continuing the premarket notification exemption for original noncompression heart stabilizers and require premarket notification submissions for these devices.

C. Environmental Impact

This petition is entitled to a categorical exclusion under 21 C.F.R. § 25.30 and § 25.31.

D. Economic Report

AMDR will submit an economic analysis upon request.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views upon which the petitioner relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

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Executive Director
Association of Medical Device Reprocesors

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