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AdvaMed
Advanced Medical Technology Association

August 7, 2003

Dockets Management Branch (HFA 305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Number 02N-0534 Medical Device User Fee and Modernization Act (MDUFAMA)

Dear Sir/Madam:

On behalf of AdvaMed, we applaud the Agency for meeting the Medical Device User Fee and Modernization Act (MDUFMA) deadline for selecting 510(k) devices and currently exempt critical devices that will require the submission of validation data meeting the new standards required by MDUFMA. We also applaud the Agency's recent corrections (in the June 26 *Federal Register* Notice) to its lists, specifically the addition of non-electric-biopsy forceps to the list of critical reprocessed single-use devices (SUDs) whose exemptions are being terminated. We sincerely appreciate the Agency's willingness to re-evaluate devices on a case-by-case basis and to update its lists appropriately. We also welcome the Agency's willingness to "consider comments from the public on additional devices that should be included in the lists at any time."

However, we do have a number of concerns regarding certain aspects of the Center for Devices and Radiological Health's implementation of the provisions within Section 302 of MDUFMA that require FDA to identify reprocessed single use devices that are exempt or have current 510(k)s that will be subject to the new requirements of MDUFMA.

As you know, with regard to exempt critical or semi-critical devices, FDA is required to identify reprocessed "devices or types of devices for which such exemptions should be terminated in order to provide a reasonable assurance of the safety and effectiveness of the devices." Any devices so identified by FDA will require the submission of validation data including cleaning, sterilization and functional performance demonstrating that the single use device will remain substantially equivalent to its predicate device after the maximum number of times the device is intended to be reprocessed. FDA is required to identify critical devices

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for which exemptions will be terminated within 6 months after the effective date of the appropriate subsection. Similarly, semi-critical currently exempt devices must be identified for 510(k) submission with validation data within 18 months after the effective date of the subsection.

Section 302 also requires FDA to identify reprocessed devices or types of devices for which reports under subsection (k) must be submitted "in order to ensure that the device is substantially equivalent to a predicate device, includ[ing] validation data regarding cleaning and sterilization, and functional performance demonstrating that the single use device will remain substantially equivalent to its predicate device after the maximum number of times the device" is intended to be reprocessed.

Summary of Concerns

Our primary concern arises from the agency's determination that the Review Prioritization Scheme (RPS) is "an appropriate risk-based tool for developing the lists required by MDUFMA because the RPS identifies the devices that are likely to raise the most concerns about both infection transmission and inadequate performance following reprocessing" and that the agency has taken steps that "adequately address concerns about the subjectivity of the RPS." AdvaMed respectfully disagrees. Specifically, we believe that any risk assessment must necessarily incorporate an objective, science-based assessment of the unique design characteristics of *each individual device* in order to properly assess and categorize the risk associated with reprocessing. We are concerned that despite the agency's efforts to appropriately augment the RPS methodology with "comments from stakeholders and an internal centerwide committee to evaluate the results of the RPS and ensure its consistency," the application of the RPS remains a subjective – and thus incomplete – method for accurately assigning risk. For these reasons, we believe the RPS method is inadequate and can result in reprocessed SUDs being inappropriately assigned to a lower risk category. We urge you to make corrections to Lists I and II. AdvaMed's specific concerns and recommendations for corrections to Lists I and II are detailed below.

Primary Concern

Congress Intended for the Spaulding Criteria to be the Primary Determinant

FDA's April 30, 2003 Federal Register Notice notes that the Agency relied, in part, upon FDA's February 2000 Review Prioritization Scheme (RPS) to determine which devices should be included in the MDUFMA-mandated lists. While MDUFMA did not explicitly prohibit the use of schemes previously developed for other purposes to identify reprocessed devices or device types of particular concern, we believe it was Congressional intent that the Spaulding criteria should be the primary mechanism used to determine whether the exempt status of reprocessed single use devices remains appropriate. In addition to including Spaulding's definitions of "critical" and "semi-critical" in the actual text of MDUFMA, the report accompanying H.R. 3580 was explicit in stating that "[t]he definitions for critical and

semi-critical devices are adopted from the criteria established by E.H. Spaulding . . ." and provided a citation for the criteria.

Congress referenced the Spaulding criteria because they intended the criteria to be the primary mechanism by which FDA identified exempt reprocessed single use devices that would require 510(k) submission and validation data. It is apparent from the Federal Register Notice that FDA "relied upon the Review Prioritization Scheme (RPS)" as a significant part of its determination of exempt devices that would now require validation data. Congress was aware of the existence of FDA's review prioritization scheme. Despite this, Congress did not discuss use of the RPS as part of its consideration for termination of exemption. As such, we do not believe Congress intended for FDA to use the RPS as part of its consideration. Further, we have a number of concerns with the use of the RPS to identify exempt devices or any other devices that will require the submission of validation data under MDUFMA.

FDA's Reliance on the Review Prioritization Scheme is Problematic

AdvaMed does not believe that the Review Prioritization Scheme (RPS) represents an *objective* risk assessment methodology for accurately identifying devices that should be subject to enhanced premarket requirements when reprocessed. In fact, in FDA's February 2000 draft guidance laying out the scheme, entitled *"Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme,"* FDA noted that the scheme was subjective: "It is important to note that many of the questions asked in the flowcharts may require subjective responses." FDA further acknowledged the difficulty of using the RPS to make consistent determinations: "Despite the possibility of different interpretations, FDA has *tried* [emphasis added] to make consistent categorizations across all SUD types."

In the final August 2000 guidance entitled *"Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals,"* FDA stated that it would not use the RPS. Specifically, FDA noted that major comments to the RPS had indicated that it lacked clarity and was subjective. In response, FDA announced that:

> "The proposed Risk Prioritization Scheme *will not be used* [emphasis added] to determine the timing of FDA's enforcement priorities for the premarket requirements. Rather, FDA will use the device classification listed in the Code of Federal Regulations (CFR) (i.e., class I, class II, or class III) to set its enforcement priorities for the premarket submission requirements."

In its April 30, *Federal Register* notice announcing the availability of the list of critical reprocessed SUDs whose exemptions were being terminated and the list of reprocessed SUDs currently subject to 510(k) requirements that would be required to submit validation data, FDA again acknowledged the problems of subjectivity and consistency associated with the use of the RPS. FDA, however, believes that the review of "an internal centerwide committee to evaluate the results of the RPS and ensure its consistency" as well as "a final

review of all the devices on these lists by the Director of the Office of Device Evaluation," "adequately address[es] concerns about the subjectivity of the RPS." We respectfully disagree.

We believe that a more objective evaluation of risk is necessary to shield FDA from criticism that it is using the inherently subjective RPS to reach pre-determined results. Moreover, because of the wide variety of device designs in any one device category, and the failure of the RPS to consider device and model-specific data, the applied methodology cannot fully determine which devices present increased risk and which do not. Failure in this area can present significant risk of harm to patients.

We respectfully submit that any application of risk of injury from reprocessing a particular device must, by necessity, take into account the specific design of the particular device in order to effectively categorize the risk of reprocessing. It is significant to note that the design control requirements of the Quality System Regulation (QSR) require manufacturers to evaluate the risks associated with the particular use *and design* of the particular device. We urge FDA to apply the same principle when evaluating the risk of reprocessing specific SUDs.

We would also note the anomaly created by FDA's use of its RPS for several exempt devices. 876.4680 Flexible Stone Dislodger, 876.4680 Metal Stone Dislodger and 872.5410 Metal Orthodontic Bracket were all simultaneously categorized as high risk and semi-critical by FDA. Since it appears that FDA used the RPS as the primary determinant – rather than the Spaulding criteria – as to which exempt products now require 510(k) submission and validation data, we urge FDA to be consistent and to immediately place these products on List I.

Specific Concerns

Corrections Needed to Lists I and II

FDA notes in the April 30 *Federal Register* Notice that "not all exempt devices that are critical have been listed." Because critical products would contact normally sterile tissue or body spaces and thus pose the greatest potential risks to patients, we strongly encourage FDA to reconsider all the products that it designated as critical in light of the specific design of each such product and to make any needed corrections to List I and List II.

It also appears that FDA did not include in List II all non-exempt devices it categorized as Risk 3. For example, 876.1500, Biliary sphincterotomes (product code FGE) was not listed. However, the same product 876.5010, Biliary sphincterotomes (product code FGE) was correctly placed on List II. It also appears that FDA left off implantable programmable infusion pumps and endotracheal tube changers. Again, we would urge FDA to immediately

place these products on List II – Reprocessed Single-Use Devices Subject to Premarket Notification Requirements That Will Now Require the Submission of Validation Data.

Product Specific Concerns
We would also like to bring to your attention a number of product specific issues associated with FDA's use of the RPS. We urge corrections in FDA's lists based on the information below.

870.4500 Vacuum assisted heart tissue stabilizing and positioning devices
Vacuum-assisted heart tissue devices are intended to stabilize and minimize the motion of selected areas of the heart during cardiac surgery and are used to perform beating heart coronary artery bypass grafts. The device uses very small lumens to draw vacuum. The device is in direct contact with the heart, thus blood and other body fluids are "sucked" into the small lumens and tubing. Retained blood or bodily fluids can provide an environment that harbors microorganisms. The ability to clean, disinfect and sterilize these small lumens pose significant concerns. In addition, if these contaminants are not completely removed, it can result in diminished vacuum capacity upon re-use. This failure mode would not likely be recognized by the physician until the device failed to perform its intended function. Loss of vacuum capture or failure to properly stabilize the anastomotic site during an anastamosis, which involves the use of scalpels, needles/sutures, etc., could result in patient injury. Device fatigue and material degradation from repeated reprocessing could also cause the device to lose stability or lose capture.

FDA has appropriately categorized the device as "critical" using the Spaulding criteria but failed to assign the device to its highest risk category under the RPS. For all of the reasons above, we recommend that the exemption for this device be terminated and that FDA immediately place the device on List I.

874.4140 Ear, nose and throat burr
Disposable ENT Blades and Burrs are "critical" devices under the Spaulding criteria. These devices, which come in contact with tissue, blood and other body fluids, contain narrow and inaccessible lumens on the inner blade, making it difficult, if not impossible, to clean portions of the device. The inability to appropriately clean and sterilize the lumens creates a substantial risk of infection from residual blood and tissue. For these reasons, FDA should have classified the device as risk 3 under the RPS. We urge FDA to immediately place these products on List I.

878.4820 Surgical instrument motors and accessories/attachments
Bits and burrs for General and Plastic Surgery applications under this classification are included on List III as devices subject to reuse but are not included on List I. As class I devices exempt from premarket notification, bits and burrs under 878.4820 should be on List I for the following reasons. First, these tools are used in cutting bone as are the bits and burrs

used in ENT applications (874.4140 included on List I) and in neurological applications (882.4310 included in List II). Second, bits and burrs under these three categories face similar issues associated with reuse, namely, cleaning and resterilization and ensuring that the original specifications associated with safe and effective cutting of bone are maintained. Third, bits and burrs are generally used interchangeably in all three applications and the original manufacturer will generally label and clear these tools for all three applications. Unless reprocessors are required to submit validation data for all three applications, it would be possible for a reprocessor to simply label bits and burrs for General and Plastic Surgery applications to avoid the requirement to submit validation data knowing full well that they will be used in Neurological and ENT applications. Therefore it is critical that bits and burrs under 878.4820 be included on List I, both on the scientific merits, and to ensure adequate and consistent regulation of bits and burrs used in these three applications.

878.4400 Electrosurgical cutting and coagulation device and accessories
We also respectfully disagree with FDA's RPS risk categorization of 2 for electrosurgical cutting and coagulation devices and their accessories. AdvaMed and others submitted comments to the docket on these products raising a number of concerns about the reprocessing of such devices. Initial use of these products can damage the dielectric coating and damage to or removal of the dielectric coating can result in electrical discharge in unintended areas of the device. Weakening of the dielectric integrity can also result in electrical arcing with adjacent steel instruments. Manual cleaning, along with chemical cleaning and disinfection agents can score the plated surfaces causing resistance between the moving parts during use. Because of the narrow and inaccessible lumens on the inner blade, it is difficult to clean critical portions of the device leading to risk of infection from residual blood and tissue. For these reasons, FDA should have classified the device as risk 3 under the RPS. We urge FDA to immediately place these products on List II.

888.1100 Arthroscope and accessories
Disposable Arthroscopic Surgery Blades and Burrs are "critical" devices under the Spaulding criteria. These devices, which come in contact with tissue, blood and other body fluids, contain narrow and inaccessible lumens on the inner blade, that make it difficult, if not impossible, to clean critical portions of the device. The inability to appropriately clean and sterilize the lumens creates a substantial risk of infection from residual blood and tissue. For these reasons, FDA should have classified the device as risk 3 under the RPS.

We would like to bring your attention to an independent study, *"Assessment of Reprocessed Arthroscopic Shavers,"* presented at the Arthroscopy Association of North America (AANA) annual conference in April, 2003. The results of the study clearly indicate that reprocessed single-use only arthroscopic shavers are frequently contaminated with DNA and protein. The study also notes that the contamination represents a risk of iatrogenic infection from various microbes, especially those that are more resistant to ethylene oxide sterilization such as viruses and prions. It further identifies significant wear both visibly and functionally in