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BY HAND DELIVERY

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

Re: Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions
From Premarket Notification; Requirement for Submission of Validation Data
(Docket 03N-0161)

Medical Device User Fee and Modernization Act (MDUFMA) (Docket 02N-0534)

Dear Sir or Madam:

The Association of Medical Device Reprocessors (AMDR) respectfully submits the following response to comments submitted to the agency on August 7, 2003 by the Advanced Medical Technology Association (AdvaMed) and by Aircast, Inc. (Aircast), regarding the agency's decision to terminate certain exemptions from premarket notification with respect to reprocessed "single use" devices (SUDs) and to require the submission of validation data for certain SUDs previously subject to the premarket notification requirement. Those actions were taken to implement the provisions of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), with respect to reprocessed SUDs.¹ AMDR is a trade association representing the legal and regulatory interests of third-party reprocessors of such SUDs. It is estimated that AMDR members perform approximately 95% of the third-party reprocessing done in the United States.

¹ Medical Device User Fee and Modernization Act (MDUFMA) of 2002; Establishment of a Public Docket, 68 Fed. Reg. 5643 (2003).

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In its comments, AdvaMed requests that FDA reconsider all “critical” devices that were not originally placed by the agency on one of the MDUFMA-mandated lists² and “make any needed corrections.” AdvaMed requests that FDA utilize the “Spaulding criteria” in determining which devices should be included on its list of critical reprocessed SUDs previously exempt from the premarket notification requirement that will now require 510(k)s with validation data. In particular, AdvaMed requests that FDA include on that list ear, nose and throat blades and burrs; certain surgical instrument motors and accessories/attachments; and certain arthroscopes and accessories. AdvaMed also urges FDA to place all non-exempt devices that were found by the agency to be “high risk” under the agency’s “risk prioritization scheme” (RPS) on its list of devices subject to the 510(k) requirement that now will require the submission of validation data.

A number of OEMs have also individually submitted comments to the agency requesting that the agency include various additional devices on the MDUFMA-mandated lists. Many of these requests are reiterations of the requests in the AdvaMed comments. In addition, AirCast has requested the agency require validation data submissions for the reprocessing of compressible limb sleeves.

I. Background

MDUFMA required FDA to review “critical” reprocessed SUDs that are currently exempt from premarket notification requirements and determine whether any of these devices requires premarket notification to provide a reasonable assurance of the safety and effectiveness of the devices.³ (“Critical” devices are defined by the agency as those SUDs intended to contact normally sterile tissue or body spaces during use.⁴) By April 26, 2003, FDA was required to identify those critical reprocessed SUDs for which the exemption from premarket notification would be terminated. MDUFMA also required FDA to review the types of reprocessed SUDs already subject to premarket notification requirements and to identify whether any of these devices requires the submission of validation data to ensure its substantial equivalence to a predicate device. FDA was required to publish a list of these devices by April 26, 2003, and to update the list as necessary.

² As described below in greater detail, MDUFMA required FDA to issue lists of reprocessed devices that would henceforth require the submission of validation data to ensure their substantial equivalence to a predicate device. FDA refers to these lists as “List I” and “List II.”

³ 21 U.S.C. § 360(o)(2).

⁴ 21 U.S.C. § 321(mm)(1).

Third-party reprocessing has an excellent safety record and AMDR, therefore, believes that there has never been a public health rationale for the agency to revoke any 510(k) exemptions or to require the premarket submission of additional validation data for any reprocessed devices. However, notwithstanding the outstanding safety record of reprocessing, in a *Federal Register* notice dated April 30, 2003,⁵ FDA issued lists identifying those critical reprocessed SUDs for which the exemption from premarket notification would be terminated, and those reprocessed SUDs already subject to premarket notification requirements for which the submission of validation data was, in the agency's view, necessary to ensure their substantial equivalence to predicate devices. FDA refers to these lists, respectively, as "List I" and "List II."

In publishing these lists, FDA indicated that it "used a number of criteria to determine which device types should be included."⁶ FDA explained,

As part of its consideration, FDA relied upon the Review Prioritization Scheme (RPS) it described in the February 2000 draft guidance document entitled, "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme." In the RPS guidance, FDA set forth factors that could be used to evaluate risk associated with reprocessed SUDs. This approach assigned an overall risk to each SUD based on (1) the risk of infection and (2) the risk of inadequate performance following reprocessing. Based on these risk factors, three categories of risk . . . were developed. The designation of "high risk" was assigned to those devices that posed the greatest risk of infection and inadequate performance after reprocessing.⁷

FDA then determined that reprocessed devices that are "high risk" according to the RPS, as well as devices that are intended to come into contact with tissue at high risk of being infected with the causative agents of Creutzfeldt-Jakob Disease (CJD), would be placed on the lists, as devices for which a 510(k) and premarket review of additional validation data are necessary in order to "provide a reasonable assurance of safety and effectiveness."⁸

⁵ 68 *Fed. Reg.* 23139 (April 30, 2003).

⁶ *Id.* at 23140.

⁷ *Id.*

⁸ *Id.*

List I contains 20 devices; List II contains 52 devices.⁹ Although AMDR continues to believe that none of the List I devices requires a 510(k) and none of the List II devices requires premarket review of validation data to provide a reasonable assurance of safety and effectiveness, AMDR's members are complying with the new submission requirements.

II. There is No Public Health Rationale for Eliminating 510(k) Exemptions or for Requiring Validation Data for Non-Exempt Devices

As noted above, the safety record for reprocessed medical devices is outstanding and, in AMDR's view, there has never been a public health rationale for the agency to revoke the 510(k) exemption for a previously exempt reprocessed device or to require that 510(k)s for non-exempt devices contain additional validation data. Of the tens of thousands of device-related adverse event reports that FDA receives through its Medical Device Reporting (MDR) program, "only a very small percentage" concern reprocessed SUDs,¹⁰ and the few problems that have occurred with reprocessed SUDs appear to be quite similar to the types of problems associated with original devices.¹¹ Further, a significant body of professional and scientific literature, much of it from peer-reviewed journals, supports the conclusion that some SUDs can safely be reprocessed.¹² As the General Accounting

⁹ As originally published, there were 15 devices on List I; FDA subsequently added non-electric biopsy forceps to the List. 68 Fed. Reg. 38071 (June 26, 2003); Orthodontic appliances and accessories, ureteral stone dislodgers and tracheobronchial suction catheters. 69 Fed. Reg. 19433 (April 13, 2004); and noncompression heart stabilizers. 70 Fed. Reg. 56911 (September 29, 2005). FDA also added laparoscopic and endoscopic electrosurgical accessories to List II. *Id.*

¹⁰ United States General Accounting Office Report, *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, But Oversight Warranted* 3 (June 2000) [hereinafter GAO Report] at 15.

¹¹ As one example, an MDR report was submitted to FDA concerning a reprocessed EP catheter whose tip had become detached. See MDR Report Number 1062310-1999-00001. However, the identical incident also has been reported for new EP catheters. See MDR Report Numbers 4501350000-1995-0088 and 6000087-1998-00002. See also GAO Report, *supra* note 10, at 16.

¹² Recent journal articles include the following: N. Ma, A. Petit, O. Huk, L. Yahia, and M. Tabrizian, "Safety Issue of Re-Sterilization of Polyurethane Electrophysiology Catheters: a Cytotoxicity Study," 14 *Journal of Biomaterials Science, Polymer Edition* 213 (2003); T.A. Ischinger, G. Neubauer, R. Ujlaky, H. Schatzl, and M. Bock, "Reuse of 'Single Use' Medical Devices After Quality Assured Reprocessing: Hygienic, Legal and Economic Aspects. Potential for Cost Savings in Interventional Cardiology," 92 *Z. Kardiol.* 889 (November, 2002); T.P. Kinney, R.A. Kozarek, S. Raltz, and F. Attia, "Contamination of Single-Use Biopsy Forceps: a Prospective in Vitro Analysis." 56 *Gastrointestinal Endoscopy* 209 (August 2002); D. Dunn, RN, MBA, CNOR,

Office (GAO) (now known as the Governmental Accountability Office) observed when it evaluated the safety of reprocessed SUDs,

the safety of reprocessing some types of devices has been established by well-developed clinical studies. Studies have shown both that reprocessing procedures can be safely accomplished and that patient outcomes are not adversely affected by the use of reprocessed ["single use" devices].¹³

"Reprocessing Single-Use Devices – Regulatory Roles," 75 *AORN Journal* 98 (July 2002); S. Mickelsen, BS, C. Mickelsen, BS, C. MacIndoe, BS, J. Jaramillo, S. Bass, MD, G. West, RN, and F. Kusumoto, MD, "Trends and Patterns in Electrophysiologic and Ablation Catheter Reuse in the United States," 87 *The American Journal of Cardiology* 351 (February 1, 2001); C.M. Wilcox, "Methodology of Gastroenterology and Hepatology," 10 *Gastrointestinal Endoscopy Clin N Am* 379 (April 2000); R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., T.J. Ball, M.D., D.J. Patterson, M.D., J.J. Brandabur, M.D., "Reuse of Disposable Sphincterotomes for Diagnostic and Therapeutic ERCP: A One-Year Prospective Study," 49 *Gastrointestinal Endoscopy* 39 (January 1999); S.K. Roach, R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., and S.E. Sumida, Ph.D., "In Vitro Evaluation of Integrity and Sterilization of Single-Use Argon Beam Plasma Coagulation Probes," 94 *The American Journal of Gastroenterology* 139 (January 1999); Blomstrom, Lundqvist, "The Safety of Reusing Ablation Catheters with Temperature Control and the Need for a Validation Protocol and Guidelines for Reprocessing," 21 *Pacing Clinical Electrophysiology (PACE)* 2558 (December, 1998); M. Bathina, M.D., et. al., "Safety and Efficacy of Hydrogen Peroxide Plasma Sterilization for Repeated Use of Electrophysiology Catheters," 32 *Journal of the American College of Cardiology* 1384 (November 1, 1998).

¹³ GAO Report, *supra* note 10, at 13 (internal citations omitted). The report went on, "For example, several studies have documented the safe reprocessing and reuse of EP catheters. One study of more than 14,000 EP procedures found that the overall rate of patient infections was very low and did not differ between clinical centers that reused EP catheters and centers that used each catheter only once. A later study of 69 EP catheters used in 336 procedures concluded that carefully reprocessing one model of single-use catheter up to 5 times posed no increase in health risks. Similarly, some evaluations of the reprocessing of single-use endoscopic instruments published in peer-reviewed scientific journals found that those [single use devices] could be reused at least several times without increasing patient risk."

Because of the third-party reprocessing industry's exemplary safety record, informed hospitals and physicians support the practice of reprocessing.¹⁴ The GAO interviewed hospital infection control practitioners, risk management executives, and patient safety experts, and they all reported that careful reprocessing of the types of SUDs that are amenable to proper cleaning and sterilization does not pose a risk to patient health.¹⁵

Indeed, reprocessing has received overwhelming support from the clinical community. The American Hospital Association (AHA) and the American College of Cardiology (ACC) are among the numerous health-related organizations that have made public statements in support of reprocessing. For example, Dr. Bruce Lindsay, representing the ACC and the North American Society of Pacing and Electrophysiology (NASPE) (now known as the Heart Rhythm Society), testified before the House of Representatives Commerce Committee that

[t]here are studies, all of which have been published in peer-reviewed scientific medical journals, which have evaluated the safety of reusing catheters for EP studies. All have found no evidence that the sterility of reprocessed catheters is a concern or that the incidence of infection is increased.¹⁶

At a Senate Hearing of the Health, Education, Labor and Pensions Committee, Dr. John Clough, representing AHA, testified

[m]any medical products can be safely reused as evidenced through decades of hospital experience in reprocessing both reusable devices and those labeled "for single use." The AHA is unaware of any

¹⁴ AMDR member companies serve nearly 60% of the 203 "top hospitals" as ranked in 2004 by *U.S. News & World Report* (and, in fact, serve 13 of the list's 14 "honor roll" hospitals). The *U.S. News & World Report's* hospital ranking can be found on the Internet at <http://www.usnews.com/usnews/nycu/health/hosptl/tophosp.htm>.

¹⁵ GAO Report, *supra* note 10, at 14.

¹⁶ Testimony of Bruce Lindsay, M.D., F.A.C.C., Associate Professor of Medicine, Director, Clinical EP Laboratory at Washington University School of Medicine, St. Louis, Missouri on behalf of the ACC and NASPE, before the House Commerce Comm., Subcommittee on Oversight and Investigations 5 (Feb. 10, 2000).

evidence to demonstrate a problem with reprocessing devices labeled “for single use.”¹⁷

III. AdvaMed Presents No Compelling Facts or Data in Support of its Suggestions that the Spaulding Criteria be Used to Determine Which Devices Should be Included on List I

In its comments, AdvaMed asserts that, in lieu of the RPS, FDA should use the Spaulding criteria to make determinations about whether a reprocessed device should remain 510(k)-exempt. AMDR emphatically disagrees.

Although MDUFMA adopted the Spaulding criteria as a mechanism for determining device criticality, there is no statutory requirement, regulatory basis, or public health reason to use these criteria for determining whether a reprocessed device requires a 510(k) in instances where the original device is exempt.¹⁸ Indeed, adopting such an approach would do violence to the statutory scheme, which did not mandate that all critical devices be subject to the 510(k) requirement but, instead, directed FDA to evaluate critical devices on a case-by-case basis, applying its expertise, and

¹⁷ Testimony of John Clough, M.D., Chair of Health Affairs, Cleveland Clinic Foundation, Cleveland, Ohio, on behalf of the American Hospital Association to the Senate Comm. on Health, Education, Labor and Pensions 3-4 (June 27, 2000).

¹⁸ AMDR agrees with AdvaMed that the RPS is flawed and should not be used for making determinations about which critical devices should be subject to the 510(k) requirement. FDA itself previously discarded the RPS approach, noting that it “lacked clarity and was too subjective.” 65 Fed. Reg. at 49584. The RPS was abandoned, in the agency’s words, “in light of comments demonstrating that it was arbitrary and unreliable, and that different persons applying the categories would achieve different results. Consequently, FDA no longer endorses the risk evaluations reported in the draft guidance.” Letter from Linda S. Kahan, Deputy Director for Regulations and Policy, CDRH, FDA to Beatrice Biebuyck, Esq., Boston Scientific Corporation at 2 (June 28, 2001). Nevertheless, in compiling its Lists I and II, FDA resurrected the RPS, concluding that it “is an appropriate risk-based tool for developing the lists . . . because the RPS identifies the devices that are likely to raise the most concerns about both infection transmission and inadequate performance . . .” 68 Fed. Reg. 23139, 23140 (April 30, 2003). In re-adopting the RPS, FDA apparently concluded that because the agency “had the benefit of comments from . . . an internal centerwide committee to evaluate the results of the RPS and ensure its consistency” and because there was a final review of the lists by the Director of the Office of Device Evaluation, the concerns about the subjectivity of the RPS had been “adequately addressed.” *Id.* AMDR disagrees. In AMDR’s view, the fundamental flaws in the RPS have not been eliminated. AMDR believes that the scheme remains subjective and prone to capricious application.

terminating an exemption only for those reprocessed devices “for which such exemptions should be terminated *in order to provide a reasonable assurance of the safety and effectiveness of the devices.*”¹⁹

As is evident from the structure of the statute, Congress intended that FDA utilize the Spaulding scheme to *prioritize* its review of currently marketed medical devices for purposes of assessing which of these devices should no longer be exempt from premarket notification requirements.²⁰ That is, Congress incorporated the Spaulding definitions of “critical” and “semi-critical” into the statute, and specified that it was for these devices that FDA should *consider* terminating exemptions for reprocessed SUDs. Thus, it is evident from the face of the statute that Congress did not intend that FDA utilize the Spaulding criteria for making the determination as to whether an exemption for a given device should be terminated: if Congress had intended that the Spaulding criteria guide FDA both in making a decision about the criticality of a particular device and in making a decision about whether to terminate an exemption from premarket notification requirements, Congress would not have established a two-step process in which FDA was first to determine whether a device was critical, semi-critical or non-critical *and then* determine whether each currently exempt critical and semi-critical device should continue to be exempt.

In its comment, AdvaMed notes that FDA did not include all critical 510(k)-exempt devices in List I. AdvaMed implies that this omission was an error, because all critical products contact normally sterile tissue or body spaces, and thus FDA should “reconsider” all of these devices and make “any needed corrections.”²¹ FDA, on the other hand, included in the list only those devices that were “either high risk according to the RPS or intended to come in contact with tissue at high risk of being infected with [Creutzfeldt-Jacob Disease].”²² In AMDR’s view, none of the specific device types that AdvaMed now seeks to have included in List I meets FDA’s criteria for placement on that list.

¹⁹ 21 U.S.C. § 360(o)(2)(A) (emphasis added).

²⁰ *Id.*

²¹ See Comments to MDUFMA Docket from Tara Federici, Associate Vice President of Technology, Regulatory Affairs, AdvaMed, to FDA (Aug. 7, 2003) at 4 (hereinafter, AdvaMed Comments).

²² 68 *Fed. Reg.* at 23141.

IV. List I Should Not be Expanded to Include Ear, Nose and Throat Burrs; Surgical Instrument Motors and Accessories/Attachments; or Arthroscopes and Accessories

OEMs (both individually and through their trade association) urge FDA to impose further burdens on reprocessing. Specifically, they have asked that FDA include ear, nose and throat burrs; certain surgical instrument motors and accessories/attachments; and certain arthroscopes and accessories on its list of critical reprocessed SUDs previously exempt from the premarket notification requirement that will now require 510(k)s with validation data, *i.e.*, List I.²³

AMDR strongly opposes the suggestion that List I be expanded to include ear, nose and throat burrs; certain surgical instrument motors and accessories/attachments; and certain arthroscopes and accessories. As noted above, in AMDR's view, there exists no public health rationale for terminating the 510(k) exemption of any critical reprocessed SUDs or for requiring premarket review of the validation data for any non-exempt device, and AMDR does not believe that the RPS is an appropriate paradigm to use in making determinations as to which devices should be included on List I and List II. Indeed, the cost to FDA of needlessly reviewing additional submissions would be significant. However, even assuming, *arguendo*, that the paradigm were appropriate, AMDR points out that all of these devices are low risk when assessed on the RPS and have an extremely low risk of transmitting CJD-causing agents.

Further, the recommendations of AdvaMed and the OEMs as to which products should lose their exemptions or should require validation data are based primarily on their own uninformed speculation about the ability of certain devices to be safely reprocessed. In AMDR's view, they have provided no credible scientific data to support their position with respect to any of these devices. OEMs cannot be regarded as experts on the "reprocessability" of devices that they choose to label as "single use." To the contrary, OEMs have a strong economic motivation to promote the notion that SUDs cannot be safely reprocessed, to discourage hospitals from using reprocessed devices.

A. Burrs/Blades and Surgical Motors and Accessories/Attachments

AdvaMed asserts that disposable ENT blades and burrs should have been classified as "risk 3" (high risk) under the RPS and should have been included on List I. AdvaMed bases this assertion on the unsubstantiated premise that ENT burrs and blades "contain narrow and inaccessible

²³ Aircast, Inc. has also asked that FDA require validation data submissions for the reprocessing of compressible limb sleeves.

lumens on the inner blade, making it difficult, if not impossible, to clean portions of the device . . . creating a substantial risk of infection.”²⁴

Although the assertion about narrow lumens being difficult to clean may sound plausible, it is not supported by 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 reproducers and OEMs to conduct process validation, and AMDR’s members have validated all of their cleaning and sterilization processes. AdvaMed’s assertions about narrow lumens should therefore have no impact on FDA’s decision making with respect to 510(k) exemptions. AdvaMed and the individual OEMs have presented no facts that should alter the agency’s decision that these devices need not be included on List I.

AdvaMed also urges FDA to eliminate the exemption for reprocessed bits and burrs for general surgical and plastic surgery applications. Nowhere in its request, however, does AdvaMed actually assert that these devices meet FDA’s criteria for placement on List I (*i.e.*, devices that are “high risk” according to the RPS, as well as devices that are intended to come into contact with tissue at high risk of being infected with the causative agents of CJD). AdvaMed’s position is that these devices should require a 510(k) because, among other things, they are used in cutting bone, as are the bits and burrs used in ENT applications and neurological applications; and (2) bits and burrs for general surgery are difficult to clean and resterilize.

AMDR disagrees. As noted above, reproducers have validated processes for cleaning, sterilization and maintenance of the functional performance of these devices. During validation, these devices are thoroughly tested to demonstrate removal of hemoglobin, protein, carbohydrates and bioburden from all parts of the device. Thus, AdvaMed’s unsupported assertions that the cleaning and sterilization functions are “difficult” should carry no persuasive weight with the agency.

B. Arthroscopes and Accessories

AdvaMed asserts that arthroscopic blades and burrs “contain narrow and inaccessible lumens on the inner blade, making it difficult, if not impossible, to clean portions of the device . . . creating a

²⁴ AdvaMed Comments, *supra* note 21 at 5. Although AdvaMed characterizes its comments as addressing ENT burrs and blades, the organization’s references to “inner blade lumens” suggest that the comments are in fact directed at ENT shavers. However, the 510(k) exemption for reprocessed ENT shavers has already been eliminated.

substantial risk of infection.”²⁵ These issues are identical to the issues identified above for general surgery blades and burrs, because the blades and burrs used in both orthopedic and arthroscopic procedures are essentially identical. As described above, AMDR’s members have validated their cleaning and sterilization processes, and there is no evidence that reprocessing of these devices increases a patient’s risk of infection.

AdvaMed relies in part on an “independent study” entitled “Assessment of Reprocessed Arthroscopic Shavers,” which it asserts “clearly indicates that reprocessed single-use only arthroscopic shavers are frequently contaminated with DNA and protein. . . . [and that] the contamination represents a risk of iatrogenic infection.... It further identifies significant wear both visibly and functionally . . . which may affect the clinical outcome of certain surgeries.”²⁶ Thus, the “independent study,” which was in fact sponsored by Smith & Nephew, is simply an abstract that was presented at the Arthroscopy Association of North America (AANA) in February, 2004. It must be pointed out, further, that AMDR is aware that the authors of the study initially submitted it for publication in *Arthroscopy: The Journal of Arthroscopic and Related Surgery*. However, AMDR understands that, due to concerns about the integrity of the samples studied, the authors have voluntarily withdrawn this “study” from consideration for publication in the journal. The staff of the journal has confirmed this information. AMDR respectfully submits that the withdrawal of the study from consideration for publication casts sufficient doubt on the validity of the findings, such that FDA cannot reasonably use the results of the study to support any regulatory decisions.

III. Compressible Limb Sleeves Do Not Require Validation Data

Aircast has requested that FDA require validation data submissions for the reprocessing of compressible limb sleeves. It is the position of Aircast that 510(k)s for compressible limb sleeves should require the submission of validation data, because “the safety and effectiveness of reprocessed [compressible limb sleeves] cannot adequately be assured without premarket review to ensure their substantial equivalence to the single use predicate device after the maximum number of times the device is to be reprocessed. . . . [R]eprocessing of [compressible limb sleeves] may compromise their physical integrity, increasing the risk of malfunction and consequently danger to patients who require them.”²⁷

²⁵ AdvaMed Comments, *supra* note 21, at 6.

²⁶ *Id.*

²⁷ See Comments to MDUFMA docket from Daniel Berish, Vice President of Government Affairs, Aircast, Inc. to FDA (April 7, 2003) at 1.

However, Aircast's comments do not suggest that compressible limb sleeves are either "high risk" according to the RPS or that they are intended to come into contact with CJD-causing agents. Thus, compressible limb sleeves are not in the category of devices for which FDA has determined that the submission of validation data is necessary.

In support of its request, Aircast argues that compressible limb sleeves degrade over time (even without reprocessing) and that reprocessing hastens the degradation process (particularly, but apparently not exclusively, with respect to the hook and loop closures), and that the submission of validation data is necessary to demonstrate that the reprocessed compressible limb sleeves are substantially equivalent to a predicate (original) device. Aircast also argues that repeated or extreme exposure to gamma irradiation (which it says is commonly used to sterilize reprocessed compressible limb sleeves) will compromise the integrity and effectiveness of the compressible limb sleeve. In particular, negative effects are alleged on the male luer lock, the hook and loop closures, and the aircell and aircell seal. Aircast therefore argues that reprocessors should be required to submit validation data demonstrating that reprocessed devices are substantially equivalent to the predicate.

Contrary to Aircast's statements, however, AMDR's members do not subject compressible limb sleeves to gamma irradiation. Sterilization is accomplished, instead, with ethylene oxide. Thus, Aircast's points about degradation under gamma irradiation are moot. Second, compressible limb sleeves that are reprocessed are inspected for functionality. Loss of physical integrity results in rejection of the sleeve in question. In addition, AMDR's members who reprocess compressible limb sleeves have all completed end-of-use reliability and mechanical validation testing. These data are documented at their facilities, as required by the QSR.

In short, AMDR respectfully submits that there is nothing in Aircast's submission that should persuade the agency that the submission of validation data is necessary or appropriate. These devices are easy to clean and sterilize, and can withstand repeated use, a fact corroborated by at least one major manufacturer of such devices.²⁸ AMDR's members have validated their cleaning and sterilization processes for these devices. Moreover, compressible limb sleeves are inspected after reprocessing to ensure that the device that is returned to service is fully functional.

IV. Conclusion

In conclusion, AMDR submits that AdvaMed and the OEMs who have requested that FDA add more devices to the MDUFMA-mandated lists have failed to present a credible public health rationale for doing so. In AMDR's view, no such public health rationale exists. Therefore, AMDR

²⁸ In *Kendall Co. v. Progressive Medical Technology, Inc.*, 85 F.3d 1570 (Fed. Cir. (MI) 1996), "Kendall argued that ...the[ir] sleeves were not physically worn-out when they were replaced and could have been used repeatedly for three years or more before wearing out."

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strongly urges FDA to preserve the 510(k) exemption for all currently exempt reprocessed devices, and to refrain from requiring validation data for any additional non-exempt devices.

AMDR appreciates the opportunity to provide FDA with comments on this important matter. Should the agency have any questions regarding the information presented in this document, please do not hesitate to contact us.

Respectfully submitted,



Pamela J. Furman, Esq.
Executive Director

PJF:la

cc: Daniel Schultz
Timothy Ulatowski
Barbara Zimmerman