

April 11, 2000

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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: Docket No. 00D-0053

Dear Sir or Madam:

The Association of Medical Device Reprocessors (AMDR) respectfully submits the following comments in response to the Food and Drug Administration's (FDA) draft guidance documents entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme," and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." 65 Fed. Reg. 7,027 (Feb. 11, 2000) (hereafter, "draft guidance documents"). AMDR is a Washington, D.C.-based trade association representing the legal and regulatory interests of third-party reprocessors of medical devices labeled for single use. It is estimated that AMDR members perform approximately 80% of the third-party reprocessing done in the United States.

AMDR is pleased to have the opportunity to provide comments on FDA's draft guidance documents. AMDR has always believed that strong FDA regulation of medical device reprocessing is critical to ensuring the safety of reprocessed devices, and we appreciate FDA's timely and comprehensive response to this matter.

In AMDR's view, however, the premarket review scheme first introduced in FDA's "Proposed Strategy on Reuse of Single-Use Devices," 64 Fed. Reg. 59,872 (Nov. 3, 1999), (hereafter, "Proposed Strategy"), and further described in the draft guidance documents, is unnecessary to protect public health, and could result in a dramatic increase in the country's already spiraling health care costs. As described in Section I below, proper medical device reprocessing is

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a patient-safe practice embraced by America's finest hospitals and physicians as a way to achieve significant cost savings without compromising patient care. If reprocessing is eliminated as an option for hospitals, certain medical devices and procedures will no longer be available for some patients, because they simply will be too expensive. Thus, "over-regulation" of reprocessing would have a direct, negative impact on patients.

From AMDR's perspective, patient safety always must be the highest priority. As discussed in Section I, the safety record of third-party reprocessing under the current regulatory regime has been excellent, and there is no evidence to suggest that a premarket review scheme is necessary to protect public health. However, despite this lack of evidence, it is clear that FDA is, nonetheless, moving forward to impose a premarket review scheme. As such, AMDR seeks to work with the agency to assure that its premarket review scheme is implemented in a reasonable manner, taking into account the strong evidence of the safety of medical device reprocessing, as well as the potentially serious consequences of unnecessarily restricting reprocessing. In Section II below, we provide detailed comments on both draft guidance documents.

I. Given the Strong Evidence of the Safety of Medical Device Reprocessing, FDA's Premarket Review Scheme is Unnecessary to Protect Public Health.

In AMDR's view, there is one, critical element missing from the agency's premarket review scheme: Nowhere does FDA provide a compelling public health rationale for changing the current regulatory framework. Indeed, when the agency first introduced its premarket review scheme, it stated that it is "committed to reevaluating its position on the reuse of SUDs (single use devices)," and that its "primary goal is to protect the public health by assuring that the practice of reprocessing and reusing SUDs is based on good science." Proposed Strategy at 7. However, neither the Proposed Strategy nor the draft guidance documents present any evidence that reprocessing has posed or is posing a threat to public health.

From AMDR's perspective, it is not surprising that the agency has failed to demonstrate a public health necessity for disrupting the current regulatory regime and replacing it with a premarket review scheme. As discussed below, not only is there no evidence to indicate that reprocessing threatens public health, to the contrary, there is substantial, affirmative evidence showing that proper reprocessing is safe. Given the demonstrated safety of reprocessing, the costly and burdensome premarket review framework proposed by FDA is unwarranted. Rather, the current regime -- which emphasizes compliance with Quality System Regulation (QSR) requirements -- is well-suited to protecting public health.

A. Done properly, medical device reprocessing is safe.

1. Hospital and physician perspective

As FDA acknowledges in its Proposed Strategy, United States hospitals have been reprocessing medical devices labeled for single-use for over two decades. See Proposed Strategy at 2. According to most estimates, at least 50% of U.S. hospitals reprocess some devices labeled for single use -- either at in-hospital reprocessing centers or through the use of third-party reprocessors.¹ Reprocessing is standard practice at a broad spectrum of health care institutions, including many of the nation's top research hospitals.

The inception of medical device reprocessing can be traced to arbitrary label changes on a number of medical devices: Approximately two decades ago, manufacturers began to change the label on certain devices from reusable to single use, without making any structural changes in the devices. Thus, it quickly became evident to hospitals that "single use" does not necessarily mean "single use," and that certain devices designated by original equipment manufacturers (OEMs) as "single use only" can, in fact, be safely reprocessed. Examples of the arbitrariness of the single use label are abundant:

- In a 1980 letter to a hospital-customer, USCI Cardiology & Radiology Products (USCI) explained that, although it was changing the label on its intracardiac electrodes from reusable to single use, "our manufacturing processes . . . have not changed. These electrodes are made with the same materials and in the same manner they have been in the past." (**Attachment A**).
- In a 1987 letter, Boston Scientific Corporation's Microvase division informed a hospital that its "BICAP Hemostatic Probes are recommended for single use only. However this recommendation does not prohibit reuse under certain specific conditions" (**Attachment B**)
- The December 11, 1998, episode of NBC's news magazine "Dateline" exposed Johnson & Johnson's practice of labeling as "single use" contact lenses that were virtually identical to the lenses that the company had been marketing as reusable. When asked why it had designated the lenses as single

¹ See, e.g., "Survey: ORs are split on reuse of single-use items," OR Manager, Vol. 15, No. 9 (Sept. 1999).

Letter to Letter to Dockets Management Branch

April 11, 2000

Page 4

use, Johnson & Johnson stated: "If we had changed the label and marketed for general use, then we couldn't advertise and create this single-use, daily disposable category. We made that decision because we felt it was a good business decision to do it that way."²

Given that the single use label is, in many cases, a "business decision" rather than a patient safety decision, it is not surprising that the medical community regards the reprocessing of "single use" devices as a patient-safe practice that allows precious health care resources to be directed toward what matters most: providing patients with the best possible care. Indeed, Dr. William Jarvis of the Centers for Disease Control and Prevention (CDC) recently observed that, with regard to the reuse of devices labeled for single use, he "would just be absolutely amazed if this is a major public health problem and the (leading hospitals) have failed to realize it."³ As detailed below, hospital and physician groups have articulated overwhelming support for the safety of reprocessing:

- The American College of Cardiology has stated: "When it comes to treating patients, our number one concern is patient safety. The reprocessed medical devices used in diagnosing and treating cardiac patients are in fact safe and effective." (**Attachment C**)
- The North American Society of Pacing and Electrophysiology has stated: "After studying thousands of patients who have undergone cardiology procedures with re-sterilized catheters, findings indicate there is no increased risk of infection for patients. Re-sterilization of cardiac catheters for electrophysiology studies has been an ongoing practice for over twenty years with no known patient adverse outcomes." (**Attachment D**)
- The American Hospital Association has stated: "The clinical use of reprocessed medical devices is safe, effective, and efficient. Hospitals have reprocessed devices labeled 'single use' or 'disposable' for years with excellent success." (**Attachment E**)

See also Letter from Dr. Stephen Hammill, Director, Electrocardiography and Electrophysiology Laboratories, Mayo Clinic, to Senator Paul Wellstone (June 23, 1998) (**Attachment F**).

² Transcript of December 11, 1998, Dateline episode at 5 (emphasis added).

³ Neergaard, Luran, "Debate on Reuse of Medical Devices," Associated Press (Aug. 13, 1999).

Thus, the message emanating from the doctors and hospitals who use reprocessed devices every day -- and who have done so for over two decades -- is clear and consistent: Properly reprocessed devices are safe and effective; there simply is no factual basis to support the notion that medical device reprocessing poses a threat to public health.

2. Scientific support

A significant body of independent, peer-reviewed scientific literature confirms the medical community's confidence in the safety of reprocessing devices labeled as single use. Indeed, studies demonstrating the safety and efficacy of reprocessing have been published in a number of highly esteemed medical journals, including *Gastrointestinal Endoscopy*, *The American Journal of Gastroenterology*, *Journal of the American College of Cardiology*, *Journal of Thoracic Cardiovascular Surgery*, *Pacing and Clinical Electrophysiology (PACE)*, *American Journal of Cardiology*, *Medical Journal of Australia*, *Canadian Journal of Surgery*, and *Canadian Journal of Cardiology*.⁴

For example, the work of Dr. Richard Kozarek, Chief of Gastroenterology at the Virginia Mason Medical Center in Seattle, Washington, and former President of the American Society for Gastrointestinal Endoscopy, has been published in *Gastrointestinal Endoscopy* and the *American Journal of Gastroenterology*. Dr. Kozarek has conducted a number of independent studies demonstrating the reusability of certain endoscopic accessories. In the area of sphincterotomes labeled as single use, for instance, Dr. Kozarek found that "[d]ouble channel sphincterotomes marketed as one-time-use items can be reused safely when properly cleaned."⁵ Likewise, with respect to argon beam plasma coagulation (APC) probes labeled for single use, Dr. Kozarek concluded:

The combination of manual cleaning and ETO sterilization consistently cleaned APC probes. Ninety percent of the probes showed no sign of physical deterioration and 100% maintained their electrical activity after 10 uses. APC probes can potentially

⁴ We have enclosed a bibliography and summary of these studies as **Attachment G**.

⁵ R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., T.J. Ball, M.D., J.J. Brandabur, M.D., "Reuse of disposable sphincterotomes for diagnostic and therapeutic ERCP; a one-year prospective study." *Gastrointestinal Endoscopy*, Vol. 49 (1999) at 39.

be safely and effectively reused up to 10 times, and a significant procedural savings is possible with reuse."⁶

As another example, Dr. Edward V. Platia, a nationally recognized electrophysiologist at the Washington Hospital Center in Washington, D.C., conducted an extensive multi-center study of the reuse of electrophysiology (EP) catheters, involving 14,640 EP cases and 48,075 catheter uses. Dr. Platia concluded that

the sterilization and reuse of non-lumen, woven Dacron pacing catheters is safe, and does not appear to result in any increase in the risk of infection. The catheters are sufficiently durable to allow them to be reused well in excess of five times. One-time use of such catheters appears to be an unnecessary and expensive policy.⁷

What is, perhaps, most striking about the rigorous body of scientific evidence supporting the safety and efficacy of reprocessed devices is its dramatically superior quality, as compared to the "studies" offered by the OEMs that oppose reprocessing. Indeed, most of the "scientific evidence" submitted by the opponents of reprocessing should be disregarded, as (i) much of it is based on "studies" conducted or sponsored by the OEMs themselves, rather than independent entities, and, as such, is tainted by the OEMs' clear economic incentive to portray reprocessing in a negative light; and (ii) much of it is plagued by fundamental scientific deficiencies, such as lack of an adequate sample size, and, as a result, cannot serve as a basis for any conclusions about the safety of reprocessed devices.

3. The safety record of reprocessing

Based on FDA's own database of device-related patient adverse events, the safety record of reprocessing is excellent. Pursuant to the agency's Medical Device Reporting (MDR) regulation, hospitals must notify FDA when they learn that a device may have caused or contributed to a patient death or serious injury. 21 C.F.R. § 803.30. Every year, FDA receives over 100,000 MDR reports. Significantly, there have been only a handful of MDR reports associated with reprocessed devices. Indeed, FDA itself recently remarked that the number of MDR reports involving reprocessed devices

⁶ 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," The American Journal of Gastroenterology, Vol. 94 (1999) at 139.

⁷ S. O'Donoghue, E.V. Platia, M.D., "Reuse of Pacing Catheters: A Survey of Safety and Efficacy," PACE, Vol. 11 (Sept. 1988) at 1280.

is "tiny" compared with other problems.⁸ Furthermore, the incidents reported in the few MDRs involving reprocessed devices are identical to problems that have occurred in new devices. Thus, it is not at all clear that these incidents were caused by reprocessing.⁹

Despite the excellent safety record of reprocessing, OEMs continue to pressure FDA, Congress, and State legislatures to address the "safety problem" posed by reprocessing. From AMDR's perspective, the OEMs' efforts are particularly troubling, given that the safety record of reprocessed devices is as good or better than the safety record of new single-use devices. Indeed, new single use devices account for several thousand more reports of patient injury and device malfunction than reprocessed devices.¹⁰

For example, a 1994 outbreak of post-surgical infections has been attributed to bacteria-contaminated sutures manufactured by a division of Johnson & Johnson, a member of the Association of Disposable Device Manufacturers (ADDM) and one of the primary opponents of reprocessing. The contamination allegedly resulted from a malfunction in the company's sterilization system.¹¹ As another example, FDA recently found that an improperly functioning coronary stent system manufactured by Boston Scientific Corporation (BSC) -- another ADDM

⁸ See Device & Diagnostics Letter, Vol. 26, No. 48 (Dec. 17, 1999) at 1.

⁹ As one example, an MDR report was submitted to FDA concerning a reprocessed electrophysiology (EP) catheter whose tip became detached. See MDR Report Number 1062310-1999-00001 (**Attachment H**). However, the identical incident has been reported for new EP catheters. See MDR Report Numbers 4501350000-1995-0088 and 6000087-1998-00002 (**Attachment I**).

¹⁰ We are enclosing as **Attachment J** a table comparing the number of MDR reports for new single use devices with the number of MDR reports for reprocessed devices.

¹¹ See, e.g., Lance Williams, "Common thread in illnesses: sutures lawsuits blame postsurgical infections on a single source," San Francisco Examiner (Feb. 21, 1999); Lance Williams, "Patients wounded by infections across the country, lives have been torn by post-op complications," San Francisco Examiner (Feb. 21, 1999); Lance Williams, "How suture maker kept lid on infection suits despite recall, Ethicon said product was harmless," San Francisco Examiner (Feb. 22, 1999); Lance Williams, "Patients who suffered," San Francisco Examiner (Feb. 22, 1999).

member -- caused 26 patient injuries, and may have been a factor in the death of one individual.¹² Thus, the truth is that the very companies who are clamoring for a "crackdown" on the alleged "public health threat" associated with reprocessing are responsible for manufacturing devices which, on their first use, have very likely caused serious patient injury.

4. FDA's Statements

FDA's observation regarding the scarcity of MDR reports involving reprocessed devices is not the only time the agency has commented on the striking lack of evidence indicating a safety problem with reprocessing. In May 1999, for example, the Medical Device Manufacturers Association (MDMA) submitted a Citizen Petition to FDA requesting that reprocessing be banned. Five months later, FDA denied MDMA's request, explaining that the agency

has received adverse event reports where a reprocessed single use device was involved; however, in each of those cases, it was not clear that reprocessing caused the problem reported. In fact, FDA has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source.¹³

Similarly, in July 1998, FDA denied a Citizen Petition submitted by the Health Industry Manufacturers Association (HIMA), in which HIMA had requested that the agency impose premarket clearance requirements on third-party reprocessors. In its denial letter, the agency stated, among other things, that "FDA notes the general absence of adverse patient outcomes attributed to the reuse of single-use devices."¹⁴

¹² See, e.g., Ronald Rosenberg, "Boston Scientific, FDA spar over stent," The Boston Globe (October 10, 1998).

¹³ Letter from Dr. David Feigal, Director, Center for Devices and Radiological Health, FDA, to Larry R. Pilot, Esq., Counsel to MDMA (October 6, 1999) (emphasis added) (**Attachment K**).

¹⁴ Letter from Bruce Burlington, M.D., Director, Center for Devices and Radiological Health, FDA, to Nancy Singer, Esq., Special Counsel, HIMA at 2 (July 13, 1998) (**Attachment L**).

B. The current regulatory regime is well-suited to protecting public health and should be maintained.

Notwithstanding the medical community's endorsement of the safety of reprocessing, the significant scientific support for reprocessing, the paucity of MDR reports involving reprocessed devices, and FDA's own observations regarding the lack of evidence indicating a safety problem with reprocessing, the agency has, nonetheless, decided to impose a costly and burdensome premarket review scheme on reprocessing. In AMDR's view, this premarket review scheme is unwarranted. Rather, the current regulatory framework governing third-party reprocessing is well-suited to ensuring the safety and efficacy of reprocessed devices.

Under the present regime, third-party reprocessors are required to comply with a number of FDA regulatory requirements, the most significant of which is the Quality System Regulation or QSR.¹⁵ The QSR is an extensive set of quality assurance provisions governing every aspect of a reprocessor's operations, including production and process controls, process validation, control of non-conforming product, and finished device acceptance. Pursuant to these QSR requirements, for example, third-party reprocessors must control and monitor production processes to ensure that a device conforms to its specifications; validate with a high degree of assurance that their reprocessing processes ensure that specified requirements are met; and establish and maintain procedures for reprocessed device acceptance to ensure that each production run, lot, or batch meets acceptance criteria. See 21 C.F.R. Part 820. In other words, reprocessors must document that they have developed comprehensive systems to assure that a reprocessed device is clean, sterile, and able to perform its originally intended clinical function. Third-party reprocessors must make all required QSR information and data available for FDA inspection¹⁶, and firms that fail to comply with these requirements are subject to agency enforcement action.

¹⁵ In addition to complying with applicable FDA requirements, AMDR members regulate themselves through adherence to several fundamental safety principles: (i) AMDR companies perform functionality testing on every single device they reprocess, whereas OEMs test only a small sampling of their devices; (ii) AMDR members are highly selective as to the devices they reprocess, and, in fact, reprocess only a small percentage of the thousands of devices used by hospitals; (iii) AMDR companies utilize sophisticated systems for tracking reprocessed devices and for enabling hospitals to trace reprocessed devices to the specific patients on whom they were used; and (iv) AMDR members must undergo an annual, independent, third-party audit to ensure compliance with QSR requirements.

¹⁶ All AMDR companies have been inspected by FDA in the last 12 months.

Given the nature of medical device reprocessing, an FDA regulatory regime focusing on QSR compliance -- and, in particular, on process validation and finished device acceptance requirements -- makes sense. Indeed, reprocessors provide a device cleaning, sterilization, and testing service for hospitals. Reprocessors do not market products; rather, they perform a process on products which, in most cases, have already been cleared through the agency's premarket review process. Therefore, from a safety perspective, what is most critical is that reprocessors validate their processes, i.e., demonstrate that their cleaning, sterilization, and testing processes will, on a consistent basis, yield devices that are as safe and effective as new devices.

Furthermore, it is important to emphasize that FDA's current QSR-centered regulatory framework for reprocessors is entirely consistent with longstanding agency policy in other areas of medical device regulation. Indeed, FDA historically has viewed demonstrated compliance with QSR requirements as an acceptable substitute for premarket notification submission in certain instances. For example, in its manual addressing compliance with QSR requirements, FDA informs manufacturers that, when manufacturers with highly qualified personnel or substantial experience feel confident that a particular change in a device, component, or manufacturing process will not significantly affect the safety or effectiveness of the device, there may be no need to submit a premarket notification submission. Medical Device Quality Systems Manual: A Small Entity Compliance Guide (December 1996) at 96.

Thus, rather than impose a new, burdensome premarket review framework on medical device reprocessing, AMDR believes that FDA should maintain the current regulatory regime. As FDA states in its draft guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (hereafter, "Enforcement Priorities draft guidance document"), under the current regime, third-party reprocessors must comply with registration, listing, QSR, labeling, MDR, and medical device corrections and removals requirements. Enforcement Priorities draft guidance document at 17. Significantly, however, while FDA has historically enforced -- and continues to enforce -- these requirements with respect to third-party reprocessors, there is an important component of the current regulatory regime, which, to date, the agency has failed to enforce with respect to OEMs. Specifically, FDA's own regulations state that

if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with other such uses to which the article is to be put.

21 C.F.R. § 801.4. As discussed above, according to most estimates, at least 50% of hospitals reuse certain devices labeled as single use. Thus, the manufacturers of these devices clearly “know[] or have knowledge of facts that would give [them] notice” that -- despite the single use label -- hospitals are using these devices more than once. As such, we respectfully request that FDA enforce § 801.4, and require manufacturers to provide adequate labeling on their “single use” devices.¹⁷

II. Given that FDA Appears to be Moving Forward to Implement a Premarket Review Scheme, AMDR Urges the Agency to Proceed in a Reasonable Manner, and is Troubled by Many Aspects of the Draft Guidance Documents.

As explained above, AMDR does not believe that FDA’s proposed premarket review scheme for reprocessing is necessary to protect public health. To the contrary, as outlined in Section I, the evidence clearly shows that the current regime is well-suited to ensuring the safety and efficacy of reprocessed devices. Nonetheless, FDA appears to be moving forward to implement a premarket review scheme. As such, AMDR is eager to provide input on the agency’s proposed scheme, to ensure that it is carried out in a reasonable manner. Moreover, AMDR notes that, pursuant to its mandate under the Food and Drug Modernization Act of 1997 (FDAMA), FDA is obligated to implement its premarket review scheme in a manner that minimizes the time and expense burden that premarket review requirements potentially could create for reprocessors. Congress through FDAMA specifically directs the agency to “consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.”¹⁸ 21 U.S.C. § 360c(a)(3)(D)(ii).

¹⁷ It is important to emphasize that AMDR does not support FDA’s proposal that OEMs include on their labeling “any information of which they are aware regarding the potential risks associated with reusing their SUDs.” Proposed Strategy at 13. In AMDR’s view, requesting OEMs to put reprocessing-related “risk” information on their labels simply would serve as an invitation for OEMs to place inflammatory and unsubstantiated statements on their products, thereby scaring hospitals away from reuse. Indeed, from a liability perspective, hospitals certainly would be reluctant to reprocess devices that are labeled with a litany of “risks” allegedly associated with reuse. Furthermore, AMDR believes there is little sense in empowering OEMs to define reprocessing-related risks. Simply because a device manufacturer believes there are certain risks associated with reprocessing a device, does not mean a third-party reprocessor would encounter those risks. OEMs have no economic incentive to prove that a device can be reprocessed, and, in fact, have every incentive to show that it cannot be reprocessed.

¹⁸ In its draft guidance document interpreting FDAMA’s “least burdensome”
(continued...)

While AMDR appreciates the daunting challenge FDA faces in implementing premarket review requirements on reprocessed devices and recognizes the amount of time and resources the agency has already devoted to this complicated issue, as discussed below, AMDR is troubled by many aspects of the agency's draft guidance documents. Most fundamentally, AMDR believes that the complex scheme contained in FDA's draft guidance document entitled "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" (hereafter, "RPS draft guidance document") is wholly unnecessary. In its RPS draft guidance document, the agency sets out an elaborate Review Prioritization Scheme (RPS) -- two flowcharts containing a series of questions -- which it uses to categorize reprocessed devices as "high," "moderate," or "low" risk. Under FDA's proposed approach, a device's risk category would determine the length of the "enforcement discretion" period permitted for compliance with premarket review requirements.

As shown below, we believe that FDA's newly-constructed risk assessment tool could lead to confusing and arbitrary results, thus making a reasonable and workable transition to a premarket review regime exceedingly difficult. Furthermore, we see no reason for FDA to invest the time and resources that would be needed to correct the serious deficiencies in the RPS and accurately apply it to the devices labeled for single use that are currently being reprocessed. Indeed, rather than attempting to construct an elaborate new "high-moderate-low" risk assessment tool, AMDR strongly urges the agency to rely on the existing device classification system as a mechanism for determining enforcement priorities. In other words, we recommend that FDA simply assign appropriate enforcement discretion periods based on the device's classification, i.e. Class I, Class II, or Class III. Given that the existing device classification system is inherently based on an assessment of a device's risk, we see no reason to depart from it. Moreover, it would ensure an orderly and predictable transition to a premarket review regime for reprocessing, because there would be no ambiguity as to whether a premarket review submission is required or when it is due. Both of these questions would be answered by ascertaining the device's classification.¹⁹

¹⁸(...continued)

provisions, the agency itself recognizes this principle. Specifically, FDA states that the agency is required to consider the "least burdensome means" that will allow appropriate premarket development and review of a product without unnecessary delays and expense to manufacturers." "Evidence Models for the Least Burdensome Means to Market," CDRH Draft Guidance (Sept. 1, 1999) (emphasis added).

¹⁹ Notably, ADDM, the trade association representing OEMs who oppose reprocessing, has expressed support for utilizing the existing device classification system as a mechanism for implementing premarket review requirements with respect to reprocessed devices.

(continued...)

AMDR recognizes, however, that FDA may, ultimately, choose to preserve its proposed approach, rather than adopting AMDR's recommendation. Thus, in the discussion below, we identify what we view as the most serious problems and inaccuracies with FDA's proposed scheme, and, where possible, we offer alternative approaches.²⁰

A. Structural problems with FDA's Review Prioritization Scheme make accurate risk designation difficult.

In its RPS draft guidance document, FDA acknowledges that "many of the questions asked in the flowcharts may require subjective responses," and further notes "the possibility of different interpretations." RPS draft guidance document at 4. In AMDR's view, FDA itself has identified the most serious problem with the RPS: It is built -- not on a foundation of objective questions and easily defined terms -- but, rather, on subjective, ambiguous questions that create confusion rather than clarity. For example, Question 3, Flowchart 1, asks:

Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection? Some design features, such as narrow lumens and interlocking parts, can harbor debris that cannot be readily accessed and removed during cleaning unless the device can be disassembled or otherwise serviced and all surfaces of the devices exposed for manual cleaning. If a device cannot be adequately cleaned, terminal reprocessing to disinfect or sterilize the device will not be successful and the SUD presents a greater risk of disease transmission. If a device does not incorporate any of these hard to clean features, then the SUD presents a low risk of disease transmission.

¹⁹(...continued)

See e.g., Letter from Josephine Torrente, President, ADDM, to FDA Dockets Management Branch (December 2, 1999).

²⁰ FDA's draft guidance documents primarily address the imposition of premarket review requirements on reprocessors, and, as such, AMDR's comments mainly focus on premarket review issues. However, the draft guidance documents also briefly describe other FDA regulatory requirements, e.g., registration and listing, medical device reporting, labeling, etc. See Enforcement Priorities draft guidance documents at 5-9. In AMDR's view, additional clarification is needed with regard to certain of these requirements, and, as such, we respectfully request the opportunity to meet with the agency to discuss these matters.

RPS draft guidance document at 6 (emphasis added). In AMDR's view, the four highlighted phrases above -- "could impede," "narrow lumens," "readily accessed," and "hard to clean" -- raise more questions than they answer, and, as such, cannot be relied upon as criteria for assigning risk. Indeed, a device that FDA or an OEM views as "hard to clean," may well be quite "easy to clean" for a third-party reprocessor who has invested time and resources in reverse engineering the device and developing a validated cleaning protocol. Similarly, any judgment as to whether features "could impede" thorough cleaning, or whether debris can be "readily accessed," or whether a lumen is "narrow," is entirely subjective. Responses to these questions will differ dramatically depending upon who is answering them.

In order to illustrate the extreme subjectivity of the RPS, AMDR applied the RPS to 14 of the 30 reprocessed devices that FDA categorized as "high risk." For all of the 14 devices examined, AMDR reached the conclusion that these devices are either "low" or "moderate" risk, not "high risk." In other words, AMDR asked the same questions that FDA asked, but reached different answers. For example, AMDR determined that electrophysiology recording catheters²¹ are "low risk" according to the following analysis:²²

Flowchart 1 - Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** - Under the "Spaulding" definition of device criticality, the electrode recording catheter or electrode recording probe engages the vascular system, meaning it enters the bloodstream.
- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** - There is substantial postmarket information that supports the safety of proper reprocessing of the electrode recording catheter and the electrode recording probe. See, for example:
 - Aton, EA, Murray, P, Frase, V, Conaway, L, Cain, ME, "Safety of Reusing Cardiac Electrophysiology Catheters: A Prospective Study," **American Journal of Cardiology**, 1994, 74: 1173-1175
 - Avitall, B, Kahn, M, Drum, D, Jazayeri, M, Hare, J, "Repeated Use of Ablation Catheters: A Prospective Study," **Journal of the American College of Cardiology**, 1993, 22: 1367-1372

²¹ Electrophysiology recording catheters (electrode recording catheters and electrode recording probes) are Class II devices. See 21 C.F.R. § 870.1220. FDA has assigned these devices product code DRF.

²² We are enclosing as Attachment M AMDR's risk assessment of 14 reprocessed devices that FDA categorized as "high risk."

- Dunnigan, A, Roberts, C, McNamara, M, Benson, DW, Benditt, DG, "Success of Re-Use of Cardiac Electrode Catheters," *American Journal of Cardiology*, 1987, 60: 807-810
- Ferrell, M, Wolf, CE, Ellenbogen, KA, Wood, MA, Clemo, HF, Gilligan, DM, "Ethylene Oxide on Electrophysiology Catheters Following Resterilization: Implications for Catheter Reuse," *American Journal of Cardiology*, 1997, 80: 1558-1561
- O'Donoghue, S, Platia, EV, "Reuse of Pacing Catheters: A Survey of Safety and Efficacy," *Pacing and Clinical Electrophysiology*, 1988, 11: 1279-1280

- 3.) *Question: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: No** - An electrode recording catheter or electrode recording probe is a sealed lumen device that is reprocessed regularly by AMDR companies without any cleaning difficulties.

AMDR CONCLUSION: LOW RISK

Flowchart 2 - Inadequate Performance Risk:

- 1.) *Question: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** - Postmarket information suggests that proper reprocessing of an electrode recording catheter or electrode recording probe poses no increased risk of injury (see articles listed in Flowchart 1).
- 2.) *Question: Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer: Yes** - The failure of an electrode recording catheter or electrode recording probe - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) *Question: Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer: No** - While the materials, coatings or components of electrode recording catheters or electrode recording probes are sometimes altered during their first use, AMDR members do not reprocess damaged electrode recording catheters or electrode recording probes. Indeed, an electrode recording catheter or electrode recording probe whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess electrode recording catheters or electrode recording probes with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any electrode recording catheter or electrode recording probe is reprocessed. Every electrode recording catheter or electrode recording probe reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the electrode recording catheter or electrode recording probe is rejected and is not returned to the hospital that had requested reprocessing.

- 2a.) *Question: Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use? AMDR Answer: No.*
- 2b.) *Question: Can visual inspection determine if performance has been affected? AMDR Answer: Yes – AMDR companies visually inspect every electrode recording catheter or electrode recording probe. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the electrode recording catheter or electrode recording probe, it is rejected and not returned to the hospital that had requested reprocessing.*

AMDR CONCLUSION: LOW RISK

As the above example and the other examples contained in Attachment M clearly demonstrate, the RPS is an inappropriate mechanism for assigning risk because the questions are subject to a range of interpretations. In addition to the subjectivity of the RPS questions, AMDR sees other structural problems with the scheme. For instance, Flowchart 2, Question 2a asks:

Are there recognized consensus performance standards, performance tests recommended by the OEMs, or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use? FDA has recognized numerous domestic and international standards that may be used for design and performance aspects of the reprocessed SUD. The list of FDA-recognized standards is available on FDA's WEBSITE. OEM-recommended performance tests (e.g., manufacturer-developed tests, standards that are not recognized) may also be applicable. In addition, there are CDRH guidance documents on FDA's WEBSITE, which may include specifications, test protocols, and acceptance criteria.

RPS guidance document at 9 (emphasis added). This question conspicuously omits any reference to reprocessor-recommended performance tests. It is reprocessors who have the most extensive knowledge base regarding how to evaluate whether a device's performance has been altered due to reprocessing and use. Thus, it is troubling to AMDR that the above question permits reliance on OEM-recommended performance tests, but fails to acknowledge the importance of reprocessor-recommended and developed performance tests.

Another significant problem with the RPS is its reliance on the "Spaulding" definitions of "critical," "semi-critical," and "non-critical" devices. As Flowchart 1, Question 1 states, under the "Spaulding" system:

- A non-critical device is a device that is intended to make topical contact and not penetrate intact skin;
- A semi-critical device is a device that is intended to contact intact mucous membranes and not penetrate normally sterile areas of the body; and
- A critical device is a device that is intended to contact normally sterile tissue or body spaces during use.

RPS draft guidance document at 5. What the flowchart fails to convey, however, is that the "Spaulding" scheme was initially designed as a mechanism for determining the appropriate level of disinfectant, and, therefore, the Spaulding definitions of criticality are of little use when it comes to evaluating the risk of a reprocessed device. Rather, a much more relevant exercise is to evaluate criticality from the standpoint of functionality, *i.e.*, what will be the consequences for the patient if the device fails? Obviously, reprocessed devices whose failure is likely to cause significant patient harm should be categorized as higher risk than those whose failure would have little or no effect on the patient.

Significantly, FDA itself has historically viewed device criticality in terms of the consequences of device failure. Indeed, in its Good Manufacturing Practice regulations, which preceded the current QSR requirements, FDA defined "critical device" as

... a device whose failure to perform when properly used in accordance with the instructions for use provided in the labeling can be reasonably expected to result in significant injury to the user.

Previous 21 C.F.R. § 820.3 (removed October 7, 1996). AMDR strongly urges FDA to utilize the above definition of device criticality, rather than relying on the Spaulding scheme.

B. FDA should disclose the detail underlying its risk assignments.

Given the structural problems with the RPS, AMDR, not surprisingly, takes issue with the risk category assigned to many of the devices in FDA's "List of Frequently Reprocessed SUDs." Indeed, as noted above, AMDR applied the RPS to 14 devices designated as "high risk," and found that each of the devices should, more accurately, be categorized as "moderate" or "low risk." However, except for the three examples provided in the RPS draft guidance document, FDA provides no information as to how it arrived at the risk assignments in its "List of Frequently

Reprocessed SUDs.” Thus, it is impossible for AMDR to identify where our analysis diverged from the agency’s, and, as such, we are hampered in our ability to offer FDA useful, thorough comments on its application of the RPS. Accordingly, we respectfully request that the agency make public the detail underlying its risk assignments, thereby enabling stakeholders to constructively challenge, or concur with, FDA’s risk assignments.

C. FDA’s “List of Frequently Reprocessed SUDs” appears to be incomplete.

It is AMDR’s understanding that, in its “List of Frequently Reprocessed SUDs,” FDA hopes to capture the entire universe of devices labeled for single use that are currently being reprocessed. Based on AMDR’s review of the list, it appears that many of the devices that AMDR members reprocess are not on the list. However, the list contains numerous ambiguities and inaccuracies, which make it difficult to verify whether all of the devices currently being reprocessed are properly represented.²³ Therefore, to ensure that FDA has a complete list, we are enclosing a database of the devices that, to the best of AMDR’s knowledge, are presently being reprocessed.²⁴ In addition, AMDR respectfully requests the opportunity to meet with FDA in order to reconcile our database with the agency’s list, so as to ensure that the agency has a complete understanding of the devices currently being reprocessed.²⁵

²³ For example, in a number of instances, devices are matched with incorrect regulation numbers and/or product codes. In addition, in some cases, FDA’s device groupings are overly broad, thus making it difficult to discern which specific products the agency intends to include.

²⁴ See Attachment N. We are also enclosing a list of devices that AMDR companies may begin reprocessing in the near future. See Attachment O.

²⁵ AMDR also respectfully requests that FDA clarify what, if any, role the “List of Frequently Reprocessed SUDs” will play once the final guidance document is issued. For example, FDA states that it “anticipates using the RPS in the future in response to requests from the public on the category of a reprocessed SUD not listed in Appendix 2. Such requests should be directed, in writing, to the contact noted in the Preface. FDA will periodically publish a revised list of categorized devices based upon these requests. . . . FDA will consider any SUD not on the current list or subsequently revised lists to be one that poses a high risk if it is reprocessed.” RPS draft guidance document at 2. These statements appear to conflict with other elements of the draft guidance documents. Thus, we respectfully request that, in its final guidance document, FDA formally address and clarify these ambiguities.

Letter to Letter to Dockets Management Branch

April 11, 2000

Page 19

D. FDA's proposed grace periods for submission of premarket review applications are unreasonably short and should be lengthened.

In its Enforcement Priorities draft guidance document, FDA proposes to require that premarket review submissions, *i.e.*, 510(k)s and PMAs, be filed for "high risk" reprocessed devices within six months of the issuance of a final guidance document. Premarket review submissions for "moderate risk" reprocessed devices would have to be filed within 12 months; submissions for "low risk" reprocessed devices would be due within 18 months of issuance of a final guidance document. Enforcement Priorities draft guidance document at 15. In AMDR's view, these grace periods are unreasonably short and should be lengthened.

Significantly, FDA's proposed grace periods are dramatically shorter than the grace periods that historically have been permitted for similarly situated entities. For example, in 1994, when FDA determined that software products used by blood establishments to manage donor information were subject to regulation as medical devices, the agency initially provided an entire year for manufacturers to submit PMAs or 510(k)s, and the agency subsequently extended the deadline for another year. See 59 Fed. Reg. 44, 991 (Aug. 31, 1994); 60 Fed. Reg. 51, 802 (Oct. 3, 1995).

Likewise, when Congress enacted the Medical Device Amendments of 1976, manufacturers of pre-amendment devices were allowed a minimum of 30 months from the time a device was classified as Class III to submit a PMA. 21 U.S.C. § 351(f)(2). In contrast, FDA proposes to require reprocessors to submit PMAs within 6 months.

As Congress clearly recognized, firms unaccustomed to complying with FDA's premarket review requirements must be given adequate time to prepare proper submissions. Indeed, a company traditionally subject to premarket review requirements would be unable to assemble a satisfactory PMA within six months. To impose such a deadline on an industry that is facing premarket review requirements for the first time -- and for numerous different devices -- is not only unprecedented, it is unnecessary and unfair. If there were compelling evidence that protection of the public health warranted requiring such a draconian grace period, AMDR would, of course, support FDA's proposal. However, the facts clearly show that no such public health threat exists. Indeed, FDA itself acknowledges that it has "been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source."²⁶

²⁶ Letter from Dr. David Feigal, Director, Center for Devices and Radiological Health, FDA, to Larry R. Pilot, Esq., Counsel to MDMA (October 6, 1999) (emphasis added) (**Attachment K**).

Letter to Letter to Dockets Management Branch

April 11, 2000

Page 20

In fact, AMDR is concerned that the public health may well be harmed if FDA maintains its proposed grace periods. Confronted with impossibly short deadlines for submitting premarket review applications on numerous devices, reprocessors may be compelled to stop reprocessing certain devices. As a result, hospitals could face shortages of important devices and be forced to discontinue providing certain medical procedures. For patients in need of such procedures, the implications are potentially devastating.

Therefore, as an alternative to FDA's approach, AMDR respectfully requests that the agency increase each proposed grace period by at least six months. Accordingly, premarket review submissions for "high risk" devices would have to be submitted within 12 months of the issuance of a final guidance document. Submissions for "moderate" and "low risk" devices would be due within 18 and 24 months, respectively.²⁷

E. "Enforcement discretion" periods should not depend upon FDA responding to the reprocessor's premarket review submission within a predetermined timeframe.

In addition to our above objections to the length of FDA's proposed grace periods, AMDR strongly objects to the notion that, under FDA's draft guidance documents, the duration of agency "enforcement discretion" would depend upon FDA responding to premarket review submissions for reprocessed devices within a predetermined timeframe. For example, FDA states that it intends to continue to exercise its discretion to not enforce premarket requirements for third party reprocessors and hospital reprocessors of devices that are considered high risk for one (1) year from the date of issuance of a final SUD enforcement guidance provided:

1. FDA receives a 510(k) submission or a PMA application within six (6) months of the issuance of the final SUD enforcement guidance;
2. The 510(k) submission or PMA application is complete and is of sufficient quality to be acceptable for substantive review . . . ; and

²⁷ If, as AMDR strongly urges, FDA abandons the RPS, and instead simply assigns submission grace periods to each device class, AMDR recommends the following grace periods: 12 months for Class III devices, 18 months for Class II devices, and 24 months for Class I devices.

Letter to Letter to Dockets Management Branch

April 11, 2000

Page 21

3. The applicant receives an FDA order finding the device substantially equivalent and cleared for marketing, or an order approving a premarket approval application within six (6) months of the filing date.

Enforcement Priorities draft guidance document at 15 (emphasis added). According to this criteria, a reprocessor that submits an administratively complete premarket review application within the specified grace period would, nonetheless, be forced to stop reprocessing the device in question if FDA takes longer than six months to respond to the application.

AMDR strongly objects to such an approach. Because of agency resource constraints, delay in reviewing and responding to premarket review applications is common, and, given that FDA reviewers have little experience with submissions for reprocessed devices, there is likely to be more delay than normal. Moreover, in proposing to penalize an industry because of FDA's failure to approve or deny a submission within a predetermined timeframe, the agency has, once again, dramatically departed from prior practice. Indeed, as described in the example above, manufacturers of pre-amendment devices are permitted at least 30 months from the time a device is classified as Class III to submit a PMA. As long as the manufacturer submits a timely PMA, its device may remain on the market until the PMA is approved or denied -- even if the approval/denial process takes several years. In other words, manufacturers of pre-amendment Class III devices are not forced to stop marketing their products simply because FDA fails to respond within a predetermined timeframe.

Thus, AMDR strongly urges the agency to eliminate any link between the duration of agency enforcement discretion and the agency approving or denying premarket review submissions within a pre-set time period. Rather, reprocessors who file timely and administratively complete submissions should be permitted to continue reprocessing until their applications are approved or denied -- regardless of how long this process takes.

F. Submission of an "administratively incomplete" application should not terminate FDA's exercise of enforcement discretion.

AMDR also is concerned that, under FDA's proposed scheme, it appears that submission of an "administratively incomplete" premarket review submission could automatically terminate FDA's enforcement discretion with respect to premarket review requirements. The agency states, in pertinent part:

Letter to Letter to Dockets Management Branch

April 11, 2000

Page 22

FDA will initially review your 510(k) submission or PMA application to make a threshold determination as to whether it contains sufficient information to begin substantive review. If the submission does not on its face, contain all the information required under 21 C.F.R. 807.87 (for 510(k)s) or 21 C.F.R. 814.20 (for PMAs), FDA will not review that application or submission any further and the file will be placed on hold. . . . You may submit the additional information to complete the file, but FDA does not intend to exercise enforcement discretion described in this document for reprocessed SUDs that are not the subject of complete applications or submissions. In other words, FDA may take immediate enforcement action for failure to comply with premarket requirements upon determining that a 510(k) submission or PMA application is administratively incomplete.

Enforcement Priorities draft guidance document at 12.

According to the above provision, if FDA were to find a reprocessor's premarket review submission "administratively incomplete," this would trigger an end to agency enforcement discretion, and the reprocessor would be vulnerable to enforcement action for failure to comply with premarket review requirements -- even if FDA's finding of "administrative incompleteness" came before the reprocessor's grace period for submission had ended. Thus, if, hypothetically, a final guidance document were issued on July 1, 2000, under FDA's proposed scheme, reprocessors would have one year -- until July 1, 2001 -- to submit premarket review applications for "moderate risk" devices. The above language suggests that a reprocessor who submitted a premarket review application on August 1, 2000, and learned on September 1, 2000 that the application was "administratively incomplete," would, as of September 1, 2000, be subject to FDA enforcement action for failure to comply with premarket review requirements -- even though that reprocessor could have waited until July 1, 2001 to initially submit its application.

In informal conversations with FDA, AMDR was told that the agency did not intend for the above provision to deprive reprocessors of the benefit of a full grace period for submission of their premarket review applications. When presented with the above hypothetical, the agency informed AMDR that a reprocessor who learned on September 1, 2000 that its application was "administratively incomplete" would continue to enjoy agency enforcement discretion with respect to premarket review requirements until the specified grace period had ended, *i.e.*, July 1, 2001. AMDR respectfully requests that, in the final guidance document, FDA formally address and clarify this issue.

AMDR also respectfully requests that, in its final guidance document, FDA specify that, as long as a reprocessor files a timely premarket review submission -- even if the submission is filed at or near the very end of the designated grace period -- the reprocessor will be permitted an additional 60 days to make appropriate modifications, if FDA finds that the application is "administratively incomplete." FDA would exercise enforcement discretion with respect to premarket review requirements during this 60-day period, and, as long as the re-submitted application were found to be "administratively complete," enforcement discretion would continue. However, if FDA determined that the re-submitted application was "administratively incomplete," enforcement discretion would cease, and the reprocessor would be subject to enforcement action for failure to comply with premarket review requirements.

Given that the reprocessing industry has never before been required to comply with premarket review requirements, and, further, that FDA has little experience in reviewing premarket review submissions for reprocessed devices, there will be a steep "learning curve" as reproducers become familiar with what is required for an "administratively complete" submission, and as FDA reviewers learn what a submission for a reprocessed device should look like. Thus, in AMDR's judgment, a fair and logical approach would be to permit reproducers at least one opportunity to make necessary corrections to an "administratively incomplete" premarket review submission.

G. In order to address HCFA-related Medicare reimbursement concerns, FDA should clarify its historical and ongoing rationale for using "enforcement discretion" with respect to premarket review requirements.

As FDA acknowledges in its Enforcement Priorities draft guidance document, the agency has, to date, utilized its enforcement discretion not to enforce premarket review requirements with respect to reproducers of devices labeled for single use. Enforcement Priorities draft guidance document at 14. Likewise, FDA's proposal to begin imposing premarket review requirements on reprocessed devices depends heavily on the exercise of agency enforcement discretion. Indeed, rather than requiring immediate compliance with premarket review requirements, FDA proposes to "phase-in" compliance, allowing different grace periods depending on the perceived risk of the reprocessed device. During the grace periods, the agency plans to use its enforcement discretion not to enforce premarket review requirements.

If premarket review requirements are going to be imposed at all on reproducers, implementation must be done on a gradual basis. However, AMDR is concerned about the Health Care Financing Administration-related Medicare reimbursement implications of FDA utilizing its enforcement discretion to implement a "phased-in" approach. Indeed, in the last several months, questions have arisen as to whether the Health Care Financing Administration (HCFA) will allow

reimbursement for medical procedures involving reprocessed devices. This uncertainty stems from FDA's current policy of using its enforcement discretion with respect to premarket review requirements, as well as certain FDA statements regarding the "lawfulness" of reprocessing conducted absent premarket review.²⁸

Given that the HCFA-related uncertainty surrounding FDA's use of enforcement discretion could have potentially devastating consequences for the reprocessing industry and for the thousands of hospitals that utilize reprocessed devices, AMDR strongly urges FDA to clarify its historical and ongoing rationale for using enforcement discretion with respect to premarket review requirements. As an example, we believe that including the following language in FDA's final guidance document could help to quell some of the uncertainty this issue has generated:

To date, FDA has used its enforcement discretion not to enforce premarket review requirements against third-party reproprocessors -- and will continue to use the same enforcement discretion to "phase in" the enforcement of premarket review requirements against third-party reproprocessors -- because FDA has not found sufficient evidence to suggest that reprocessing, absent FDA premarket review, presents a threat to public health.

H. FDA's proposed definitions should be revised.

In Appendix A of the Enforcement Priorities draft guidance document, FDA proposes definitions for "hospital," "single-use device," "opened-but-unused," "reuse," "reprocessing," and "resterilization." AMDR recommends the following revisions to FDA's proposed definitions:

1. Single use device

FDA proposes the following definition for "single-use device":

Single-use device: a single-use device that is intended to be used on one patient during a single procedure. It is not intended to be reprocessed (cleaned and

²⁸ See, e.g., Letter from Larry Spears, Director, Division of Enforcement III, Office of Compliance, Center for Devices and Radiological Health, to Stephen D. Terman, Esq., Olsson, Frank and Weeda, P.C. (July 9, 1999); Letter from Grant P. Bagley, M.D., Director, Coverage and Analysis Group, HCFA, to Josephine Torrente, Esq., Hyman, Phelps & McNamara, P.C. (Attachment P).

disinfected/sterilized) and used on another patient. The labeling identifies the device as disposable and does not include instructions for reprocessing. Some single-use disposable devices are marketed as non-sterile and include appropriate pre-use sterilization or processing instructions to make the device patient-ready.

AMDR is troubled by the above definition because it links the notion of single use to what the manufacturer "intends." However, it is not at all clear what "intent" means in this context. Rather, in AMDR's view, a device should come within the definition of single use only if it is labeled to be used on one patient during a single procedure. As such, AMDR recommends that the above definition be modified as follows:

Single use device: A device that is labeled to be used on one patient during a single procedure. The labeling identifies the device as disposable and does not include instructions for reprocessing. Some single use devices are marketed as non-sterile and include appropriate pre-use sterilization or processing instructions to make the device patient-ready.

2. Opened-but-unused

FDA proposed the following definition for "opened-but-unused":

Opened-but-unused: an opened-but-unused device is a single-use device whose sterility has been breached or whose sterile package was opened but the device has not been used on a patient.

As explained above, AMDR believes that any definition incorporating the notion of "single use" must be confined to explicit single use labeling. Thus, AMDR proposes to define "opened-but-unused" as follows:

Opened-but-unused: An open-but-unused device is a device that is labeled to be used on one patient during a single procedure, whose sterility has been breached or whose sterile package has been opened, but which has not been used on a patient.

Letter to Letter to Dockets Management Branch

April 11, 2000

Page 26

3. Reuse

FDA proposes the following definition for "reuse":

Reuse: the repeated use or multiple use of any medical device including reusable and single-use medical devices, on the same patient or on different patients, with applicable reprocessing (cleaning and disinfection/sterilization) between uses.

In AMDR's view, the above definition is unnecessarily repetitive and complex. Instead, AMDR recommends that "reuse" be defined as follows:

Reuse: The use of a device more than once.

4. Reprocessing

FDA proposes to define "reprocessing" as follows:

Reprocessing: includes all operations performed to render a contaminated reusable or single-use device patient ready or to allow an unused product that has been opened to be made patient ready. The steps may include cleaning and disinfection/sterilization. The manufacturer of reusable devices and single-use devices that are marketed as non-sterile should provide validated reprocessing instructions in the labeling.

AMDR believes that the above definition is incomplete because it does not include the functional testing or packaging steps of reprocessing. In addition, this definition fails to reflect that reprocessing may be performed on open but unused devices. Therefore, AMDR recommends that FDA adopt the following definition of "reprocessing":

Reprocessing: All operations performed to render a used or opened but unused device patient-ready. Reprocessing steps may include cleaning, functional testing, packaging, and sterilization. The manufacturers of reusable devices and single use devices that are marketed as non-sterile should provide validated reprocessing instructions in the labeling.

Letter to Letter to Dockets Management Branch
April 11, 2000
Page 28

that the agency considers servicers and refurbishers to be manufacturers.²⁹ It is unclear to AMDR why the agency has chosen to treat reprocessors of devices labeled for single use differently than device servicers and refurbishers.

Conspicuously missing from the manufacturers' rhetoric, however, is any acknowledgment of the economic agenda driving their campaign against reprocessing. Indeed, from the OEMs' perspective, every time a hospital safely uses a reprocessed device, rather than purchasing a new one, this is a lost sale. Thus, as FDA finalizes its draft guidance documents, AMDR urges the agency to avoid being swayed by the tremendous financial and political pressure exerted by the OEMs who oppose reprocessing. Rather, we respectfully request that FDA take into account the strong safety record of reprocessing, and the direct, negative impact on patients of unnecessarily restricting reprocessing.

* * *

AMDR appreciates the opportunity to provide comments on FDA's draft guidance documents. 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
Executive Director

PJF:la
Enclosures

²⁹ Apparently, FDA studied the risks presented by servicing and refurbishing, and concluded that "self-regulation" of this set of device manufacturers was adequate to protect public health. Indeed, rather than imposing a complex premarket review scheme on the device servicing and refurbishing industry, FDA is permitting the industry to police itself through a system of voluntary controls. See Hatem, Mary Beth, "From Regulation to Registration," Biomedical Instrumentation and Technology, Vol. 33 (Sept./Oct. 1999).

ATTACHMENT A



USCI CARDIOLOGY & RADIOLOGY PRODUCTS

July 24, 1980

Dear Dr.

I am writing this letter, as per your request, to substantiate that our manufacturing processes of Woven Dacron Intracardiac Electrodes have not changed. These electrodes are made with the same materials and in the same manner as they have been in the past.

USCI has been manufacturing intracardiac electrodes since the early 1960's. Throughout this time, USCI electrodes have been held as standards of the industry. We are proud of our heritage, but now find that current hospital and government practices makes traditional methods, such as reuse, difficult to justify and increasingly untenable for the manufacturer. USCI does not control the "reuse decision" that is yours to make, however, we do believe it is in the best interest of all concerned that a new electrode instrument be used on each case. USCI has changed its labeling and instructions to reflect this position.

To insure that our customers receive the safest product possible, and a product which is guaranteed to be within accepted specifications, all USCI Woven Dacron Electrodes have been shipped in double sterile packages as of March 1980. This new package includes two major modifications: the elimination of cleaning instructions, and a label which indicates that the product is intended for one time use. With these changes, USCI now offers a product which conforms with accepted standard for the marketplace in which we sell.

I am fully aware that these changes may impinge on certain budget restraints which you are faced with. I would be more than happy to review with you scheduled orders and quantity discounts which may be applicable. Please call me if I can be of any further assistance. I hope this information prove useful to you.

Sincerely,


Brian Dowling
Product Manager

BD/jab

Enclosures: (1) HEW Position, (2) HEW Position, (3) VA Circular, (4) HEW Position
(5) Morbidity and Mortality Weekly Report, (6) VA Circular

DIVISION OF C.R. BARD, INC., BOX 566, 129 CONCORD ROAD, BILLERICA, MA., 01821, USA.
TEL. 617-667-2511

ATTACHMENT B

May 1, 1987

Dear

As you know BICAP Probes are labeled for single use only. Reusing a probe can put a hospital and physician in an extremely precarious position legally if there would be a complication due to the probe.

Considering the price of each probe, \$165, we at Microvasive realize it is very difficult for a hospital to dispose of a probe after each use.

Enclosed you will find a letter legally allowing the reuse of Microvasive BICAP Probes. In essence, if you follow our cleaning instruction and always have an unused probe as a back up, we will legally back the reuse of our probes.

Please keep this enclosure as a document for your records and it does only apply to Microvasive BICAP Probes.

Our Probe catalog numbers are:

#4007	7 fr Probe	\$165.00
#4010	10 fr Probe	165.00
#4050	5 fr Probe	225.00 (for the Bronoscope)

Our probes will fit the ACMI as well as Microvasive BICAP's. After all, they are the same unit.

Please call if you have any questions, 800-225-3226 or 612-936-9166.

Respectfully,



Geoffrey M. Allen

GMA/jr

Enclosure

cc: Stewart Gomm

BICAP® HEMOSTATIC PROBES - SINGLE USE OR REUSE

BICAP® Hemostatic Probes are recommended for single use only. However, this recommendation does not prohibit reuse under certain specific conditions and with full knowledge of the potential consequences.

The single use recommendation is based upon the fact that each activation of any therapeutic probe induces stresses in that probe and consumes some portion of its useful life. There are no readily available means for assessing the magnitude of the induced stresses or the remaining useful life.

The useful life of the BICAP® Therapeutic Probe is strictly a function of the clinical therapeutic procedure for which no standards have been developed. Therefore, any life tests tend to report average life which is meaningless in a specific clinical application. It has been reported to us that the useful life has varied from a fraction of one complex procedure to eight simple procedures.

In order to assist physicians in making the single use or reuse decision, MICROVASIVE makes the following recommendations:

1. If the clinical indications are such that you expect a longer than average therapeutic procedure, start the procedure with a new BICAP® Hemostatic Probe.
2. Reuse a BICAP® Hemostatic Probe only after you:
 - a. Assure that the probe has been carefully cleaned.
 - b. Assure that the probe has been inspected and is acceptable.
 - c. Assure that the probe has not been subjected to disinfection/sterilization environments more severe than those stated in the Operating and Maintenance Manual.
 - d. Assure that an alternate new probe is readily available.
 - e. Accept the potential adverse consequences in the particular therapeutic procedure should the probe reach the end of its useful life before the procedure is completed.

MICROVASIVE will continue to recommend that prudent practice dictates single use of the BICAP® Hemostatic Probe rather than to start a procedure with a probe whose condition is unknown. However, we also recognize and understand the cost concerns in the clinical environment which frequently cause devices intended for single use to be reused without the benefit of a consistent criteria. Our recommendations are intended to reduce the risk of this practice.

ATTACHMENT C

AMERICAN COLLEGE of CARDIOLOGY



Heart House
9111 Old Georgetown Road
Bethesda, MD 20814-1699
USA

301-897-5100
800-253-4636
Fax: 301-897-9745
<http://www.acc.org>

June 25, 1999

The Honorable
Richard Durbin
364 Russell Senate Office Building
Washington, D.C. 20510

Dear Sen. Durbin:

It has come to the attention of the American College of Cardiology (ACC) that you are considering offering an amendment to the Agriculture, Rural Development, and Related Agencies Appropriations bill that would severely restrict the use of reprocessed medical devices. On behalf of more than 24,000 cardiovascular specialists, I wish to express the ACC's deep opposition to your amendment.

When it comes to treating patients, our number one concern is safety. The reprocessed medical devices used in diagnosing and treating cardiac patients are in fact safe and effective. In particular, the ACC is concerned about the effect your amendment will have on the use of reprocessed catheters, such as those used in electrophysiology. Solid, rigid catheters are used by cardiovascular specialists in electrophysiology for the placement and removal of pacemakers and implantable defibrillators. Generally, between two and six catheters are used during a single procedure, but it is not uncommon for as many as eight to be used. New, these catheters cost between \$150 and \$1000 each. Reprocessed catheters are not only safe and effective, they are also cost efficient.

The catheters used in electrophysiology can be used safely, following sterilization, as many as five times, thereby greatly reducing costs. Concerns that reprocessed catheters could cause serious injury to patients are completely unfounded. There are cardiovascular specialists who have been using reprocessed catheters in their labs for more than 20 years and cannot cite a single instance where a reprocessed catheter has broke or caused infection. Simply stated, your amendment will unnecessarily increase health care costs and could potentially result in the closing of electrophysiology labs.

Generally speaking, your concern for patient safety is appreciated. The ACC simply questions the claims that reprocessed medical devices, particularly those used in cardiovascular medicine pose a danger to patients. Therefore, the ACC must oppose your amendment, as it will unjustifiably increase costs, and urges you not to seek its passage until a more detailed discussion about the issue can occur.

Sincerely,

Arthur Garson, Jr., M.D., F.A.C.C.
President

Cc: Sen. Edward Kennedy
Sen. William Frist
Sen. Jim M. Jeffords

President

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ATTACHMENT D



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NASPE's Mission Statement

The mission of the North American Society of Pacing and Electrophysiology, an organization of physicians, scientists, and allied professionals throughout the world dedicated to the study and management of cardiac arrhythmias, is to improve the care of patients by promoting research, education and training, and providing leadership toward optimal healthcare policies and standards.

Executive Director
Carol J. McGlinchey

June 22, 1999

The Honorable Richard J. Durbin
Senate Russell Building
Room 364
Washington, DC 20510

Dear Senator Durbin:

The North American Society of Pacing and Electrophysiology (NASPE) is very concerned with your proposed amendment to Senate Bill 1233, titled "Reprocessed Medical Devices". This amendment would restrict the re-processing of medical devices labeled for single-use. The current medical practice of re-sterilizing medical devices, such as cardiac catheters, is not only common, but has been proven safe and effective in the care and treatment of patients with cardiac rhythm problems, also known as arrhythmias.

NASPE is an organization of physicians, scientists and allied health professionals dedicated to the study and management of cardiac arrhythmias and to improving the care of patients by promoting research, education and training. NASPE members diagnose and treat patients with cardiac rhythm problems.

There has been considerable peer-reviewed published research into the effect on patient care using re-sterilized cardiac catheters. A brief list of references is attached. After studying thousands of patients who have undergone cardiology procedures with re-sterilized catheters, findings indicate there is no increased risk of infection for patients. Re-sterilization of cardiac catheters for electrophysiology studies has been an ongoing practice for over twenty years with no known adverse patient outcomes. In addition, the Food and Drug Administration permits re-sterilization of catheters provided that a meticulous quality assurance program documents the structural integrity of the catheters, and that sterility and chemical residuals are monitored.

NASPE members foremost priority is to provide quality medical care to patients. Appropriate medical device re-processing is a safe and effective way to achieve health care cost savings without compromising patient care. These savings can be directed towards improving patient access and medical care.

Legislation, which would add new and unnecessary regulatory requirements for the reprocessing of medical devices, would hinder the practice of cardiac electrophysiology in this country. NASPE encourages you to research this topic further before passing a legislative mandate that would, in essence, ban a medically acceptable and safe practice. Hearings on this topic could include

experts in the field of medical device reprocessing, representatives of the Food and Drug Administration, physicians, as well as patient representatives.

NASPE would be pleased to provide you with additional information on this critical issue. Please feel free to call me at the Hershey Medical Center at 717-531-3907 or Amy Melnick, Director, Government Relations at NASPE. Thank you for your attention.

Sincerely,

Gerald V. Naccarelli M.D.

Gerald Naccarelli, MD
President
North American Society of Pacing and Electrophysiology

References:

- 1) O'Donoghue S, Platia EV. Reuse of Pacing Catheters: A Survey of Safety and Efficacy. PACE 1988;11:1279-1280.
- 2) Dunnigan A, Roberts C, McNamara M, Benson DW, Benditt DG. Success of Re-Use of Cardiac Electrode Catheters. American Journal of Cardiology 1987;60:807-810.
- 3) Avital B, Khan, Krum D, Jazzayeri M, Hare H. Repeated Use of Ablation Catheters: A Prospective Study. American Journal of Cardiology 1993;22:1367-1372.
- 4) Aton EA, Murray P, Frase V, Conaway L, Cain ME. Safety of Reusing Cardiac Electrophysiology Catheters. American Journal of Cardiology 1994;74:1173-1175.

ATTACHMENT E



June 23, 1999

The Honorable Thad Cochran
 United States Senate
 326 Russell Senate Office Building
 Washington, DC 20510

Dear Chairman Cochran:

The American Hospital Association (AHA), which represents nearly 5,000 hospitals, health care systems, networks, and other providers of care, wants to raise our serious concerns about an amendment that Senator Richard Durbin (D-IL) is preparing to offer to the Agriculture Appropriations bill when it comes to the Senate floor this week. The amendment would restrict reprocessing of medical devices, and could seriously affect both the quantity and quality of health care we offer our patients.

The clinical use of reprocessed medical devices is safe, effective, and efficient. Hospitals have reprocessed devices labeled "single use" or "disposable" for years with excellent success. In our view, the real issue is not whether reuse is appropriate, but whether the single use label is a complete and accurate representation of the device. With this in mind, it is the general practice for hospitals to rely on physicians, nurses, sterile processing professionals and infection control specialists to deliberate carefully before deciding to reprocess any device and ensure that proper safeguards exist in the reprocessing procedure. In-hospital reprocessing is also subject to Joint Commission on Accreditation of Healthcare Organizations oversight.

For hospitals, proper reprocessing is a safe and effective way to deliver the highest quality patient care. There is an extensive body of research demonstrating that reprocessing of certain medical devices is appropriate and poses no significant risk to patients. If the Durbin amendment is adopted, it would result in devices being disposed of after only one use, even if the device could still be used safely and effectively, contributing unnecessarily to the waste streams generated by health care facilities.

Finally, the Food and Drug Administration (FDA), whose jurisdiction includes oversight of reprocessed devices, has indicated that it shares some of our concerns regarding Sen. Durbin's amendment. The FDA agrees that more research needs to be done to determine the prevalence of reprocessing and the ability of reprocessors to maintain quality.



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 Chicago, Illinois Center for Health Care Leadership

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The Honorable Thad Cochran

Page 2

June 23, 1999

There is no quick and easy solution to this issue. The Durbin amendment is at best premature and at worst would have a far-reaching negative impact on what is a safe and standard medical practice. The whole issue deserves a much more thoughtful review before legislation is enacted. We respectfully ask that this amendment not be included in the Agriculture Appropriations bill when it comes to the Senate floor.

Thank you for your attention to this matter.

Sincerely,

A handwritten signature in black ink that reads "Rick Pollack". The signature is written in a cursive, slightly slanted style.

Rick Pollack

Executive Vice President

ATTACHMENT F



Mayo Clinic
200 First Street SW
Rochester, Minnesota 55905
507-284-2511

Stephen C. Hammill, M.D.
Cardiovascular Diseases
& Internal Medicine

June 23, 1999

The Honorable Paul Wellstone
United States Senate
Washington DC 20510

Dear Senator Wellstone:

As Professor of Medicine and Director of Electrophysiology at Saint Marys Hospital and Mayo Clinic, I am writing to express my concern about reports that Senator Richard Durbin may propose legislation to restrict the reprocessing of medical devices labeled for single use. Such legislation would have a seriously negative economic impact on our Electrophysiology Program at Saint Marys Hospital.

The Electrophysiology Program at Mayo has sought to provide the highest quality care while maintaining a cost-efficient approach. For more than 20 years, the catheters used in electrophysiology procedures have been reprocessed at Mayo and have continued to function normally without any evidence of infection. Reprocessing the catheters has allowed us to use each catheter five or six times, greatly decreasing the cost of the procedures. During electrophysiologic testing, we use between two and eight catheters per study with total catheter costs approaching \$300-\$4000. Reprocessing of the catheters has proven to be a safe and effective technique and has allowed us to gain the most use from the catheters, making them as cost efficient as possible.

I am greatly concerned that any legislation to add new and unnecessary regulatory requirements for the reprocessing of medical devices would add tremendous costs to the electrophysiology study and achieve no benefit for patients. I would appreciate you not supporting this type of legislation, and I would be happy to provide any additional information you might desire.

Sincerely,

Stephen C. Hammill, M.D.
Professor of Medicine
Director, Electrocardiography
and Electrophysiology Laboratories

SCH:mp

ATTACHMENT G

plasma sterilization was cost-effective and safe as long as it is accompanied by visual inspection of the catheters.

1997

R.A. Kozarek, M.D., S.E. Sumida, Ph.D., S.L. Raltz, R.N., M.S.N., L.D. Merriam, D.C. Irizarry. "In vitro Evaluation of Wire Integrity and Ability to Reprocess Single-Use Sphincterotomes," **Gastrointestinal Endoscopy**, February 1997, Vol. 45, No. 2, p.p. 117-121

Study to evaluate sphincterotomes' ability to be safely reprocessed without loss of form or function. Seven of ten sphincterotomes completed the study in good condition with no detected problems. Concluded that single-use sphincterotomes have the potential for safe reuse.

"What Does 'Single-Use Only' Mean to You? Reprocessing Road Map: Policies for the Reuse of Disposables," **Materials Management**, May 1997, p.p. 44-46

The article discusses suggested guidelines for hospitals to use in evaluating their needs and ability to safely reprocess single-use devices. If hospitals lack the facilities for reprocessing, the article suggests that third-party reprocessing is a good option.

"What Does 'Single-Use Only' Mean to You? The Third Degree: Ask Tough Questions Before Going Outside," **Materials Management**, May 1997, p.p.48-50

Article describes what hospitals should look for when researching third-party reprocessing and the companies that provide the service.

R. Sites, **OHA News**, "Reuse of Certain Medical Devices Encouraged," May 16, 1997

Discusses OHA's request to the Ohio Administrative Code medical board to revise their policy on reuse of single-use devices. Author states that the single-use label is an economic issue for the manufacturer. With the single-use label, manufacturers have been able to reduce their liability risks, sell more devices and eliminate the expense of testing a device to market it as reusable. The article concludes that reprocessing certain devices can save funds, ultimately benefiting the consumer with lower health care charges, lower health insurance costs, and improved access to care.

D.F. Bloom, et. al., "Technical and Economic Feasibility of Reusing Disposable Perfusion Cannulas," **Journal of Thoracic Cardiovascular Surgery**, September 1997, Vol. 114, No. 3, p.p. 448-460

Study to evaluate reusability of disposable single and dual-stage venous and arterial perfusion cannulas. Found that all devices were able to be successfully sterilized with no functionality changes detected by experienced cardiac surgeons in selective evaluation. A 64% cost savings was achieved.

Stewart, "'Single use only' labeling of medical devices: always essential or sometimes spurious?" **Medical Journal of Australia**, November 17, 1997, Vol. 167, p.p. 538-539

Article discussing the "single-use only" label wherein the author could find neither anecdotal nor factual evidence of any transmission of viral disease attributable to the reuse of cardiac electrode catheters.

Author calls the evidence supporting the single-use status of "high risk" cardiac catheters "unconvincing." Goes on to list various items that are needlessly labeled single-use, such as: disposable PVC oxygen masks, disposable...

Bibliography and Summaries of Articles Addressing Reprocessing Of Medical Devices Labeled for Single-Use

1999

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," **Gastrointestinal Endoscopy**, January 1999, Vol. 49, No.1, p.p. 39-42

Study to evaluate if disposable double-channel sphincterotomes can be sterilized and reused an average of 3.4 times. Easily detected broken or stiff cutting wires were the cause for discard. The reuse of the sphincterotomes had a total savings of \$66,000. Study concluded that double-channel sphincterotomes can be reused safely when properly cleaned and the cost benefit of doing so was substantial.

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," **The American Journal of Gastroenterology**, January 1999, Vol. 94, No. 1, p.p. 139-143

Study of argon plasma coagulation (APC) probes to determine if they could be re-sterilized and still maintain their electrical integrity. All ten of the ten probes tested completed the study in good condition, 90% of the probes showed no signs of deterioration and 100% maintained their electrical integrity. Concluded that APC probes can be safely and effectively reused ten times with significant cost savings.

Hensley, Scott, "More hospitals buy into device recycling: The practice of reprocessing disposable products is moving into the mainstream," **Modern Healthcare**, February 22, 1999

Hensley's article focuses on the decisions of hospital purchasing groups to contract out for reprocessing services to third-party reprocessors. The writer states that the trend means third-party reprocessing is gaining mainstream acceptance. The article found that hospitals that were originally using third-party reprocessors only to resterilize open and unused devices are now including previously utilized medical devices in their reprocessing service contracts. Such hospitals have confidence in their third-party reprocessors and are achieving significant cost savings.

1998

R. Kleinbeck, et. al., "Reprocessing and Reusing Surgical Products Labeled for Single-Use, A Survey of Current Practices," **Surgical Services Management**, January 1998, Vol. IV, No. 1

Kleinbeck found that third-party reprocessors have validated methods and protocols to address sterility and functionality testing issues. The article concluded that third-party reprocessing is a safer alternative than some in-hospital reprocessing programs.

M. Bathina, M.D., et. al., "Safety and Efficacy of Hydrogen Peroxide Plasma Sterilization for Repeated Use of Electrophysiology Catheters," **Journal of the American College of Cardiology**, November 1, 1998, Vol. 32, No. 5, p.p. 1384-1388

Study to evaluate technique for sterilizing nonlumen electrophysiology catheters. Found that there was no loss of electrical integrity or mechanical integrity during the study. With the reprocessor...

Author calls the evidence supporting the single-use status of "high risk" cardiac catheters "unconvincing." Goes on to list various items that are needlessly labeled single-use, such as: disposable PVC oxygen masks, disposable pressure infuser, disposable nasal oxygen prongs, single-patient-use oxygen transducers, pill cups, kidney trays, suction tubing, sequential calf compression cuffs and arm splints for intravenous lines. States that the financial and environmental cost of disposal for hospitals is increasing and should be calculated into the true cost of "single-use only" devices.

R. M. Whitby, "*Single use only: obfuscation or the necessary attainment of zero risk?*" **Medical Journal of Australia**, November 17, 1997, Vol. 167, p.p. 519-520

Discusses the benefits and risks associated with reprocessing devices. States that if high risk items are deemed as unfit for reprocessing because they are used in invasive procedures then, "... logic demands that restaurants provide 'single-use only' crockery and cutlery to each patron - as these items enter body cavities and are regularly contaminated with body fluids, they induce as much, if not more, risk of transmitting infection." Finds that it is important to determine what motivates the manufacturers to label a device "single-use only."

1996

"*Reuse of Single-Use Items*," **Infection Control & Sterilization Technology**, May 1996, p.p. 78-80

A published survey of hospitals with regard to their reuse and reprocessing policies. Found that the majority of hospitals did not have set guidelines for reprocessing. Only one hospital, Kaiser Permanente in Bellflower, CA, was able to supply a written policy on reuse and reprocessing. Found that many respondents wrote that they thought visual inspection of a device after reesterilization was sufficient. The article made a strong argument to send devices to a knowledgeable third-party reprocessor.

Turi, "*Reuse of Disposables: Let's Not Embrace Waste*," **Catheterization and Cardiovascular Diagnosis**, June 1996, Vol. 38, No. 2, p.p. 133-343.

Article addressing the cost burden of single-use items, especially on developing nations. Author finds reuse possible and necessary.

English, et. al., "*Reprocessing Disposables: One Strategy to Balance Cost Reduction and Quality Patient Care*," **Today's Surgical Nurse**, July/August 1996, p.p. 23-26

States that health care organizations must now respond to the demands to reduce costs as well as new regulations to reduce the amount of waste disposed of in landfills. Finds that many disposable devices are made from durable materials and that in Canada and Europe manufacturers have sold as "reusable" the same devices that are labeled as single-use in the United States. The author finds that the protocols required of a hospital to establish a safe and viable reprocessing center require that hospitals make a substantial investment in reprocessing. Therefore, the article recommends outsourcing to third-party reproprocessors. Also states reprocessing has a positive environmental impact, finding that disposing of hospital waste costs from 1.5 to 30 cents per pound. Reprocessing allows for less waste and reduced disposal costs.

1995

J. McCormack, "Put Those Nagging Sterilization Worries to Rest, Once and For All," **Materials Management**, September 1995, p.p. 50-51

Addresses three worries associated with sterilization: first, determining if the label chosen by a manufacturer is accurate in stating that the device is reusable or disposable, as the single-use only label may be motivated by economic or liability concerns. Second, because validated cleaning standards do not exist for items such as endoscopes, it is important for a hospital to establish cleaning methods wherein the benefits greatly outweigh the risks. The third concern is to make sure sterility monitoring devices are being used properly.

G. E. Becker, "Reposables - A Matter of Financial Survival," **Infection Control & Sterilization Technology**, October 1995, p.p. 38-40

Becker addresses central processing professionals' need to reevaluate their policies on single-use items, "Can we safely throw out items that could safely be reprocessed at least a few times?" he asks. Becker states that, "disposing of items that still have useful life is a wasteful practice that can no longer be tolerated in our financial environment." He noted that, in one case, a prominent ophthalmologist found he could successfully reuse a phaco tip for a total of six uses, saving \$90,000 per year. One supplier of these "single-use" tips began to market reusable tips as a result of the ophthalmologist's practice. The other example Becker cites involves keratome knife blades manufactured by OASIS. OASIS helped Southern California Kaiser Hospitals develop reprocessing protocols for their keratome knife blades, which OASIS said could safely be reused up to 20 times. Following their testing, Kaiser decided to reuse the blades ten times as a cost savings of approximately \$80,000 per year.

J.G. DesCôteaux, M.D., et. al., "Reuse of Disposable Laparoscopic Instruments: A Study of Related Surgical Complications," **Canadian Journal of Surgery**, December 1995, Vol. 38, No. 6, p.p. 497-500

Study of surgical complications due to reuse of disposable laparoscopic instruments. Concluded that the instruments may be safely reused under "carefully monitored conditions with strict guidelines."

1994

"The Re-Use of Single use Cardiac Catheters: Safety, Economical, Ethical, and Legal Issues," **Canadian Journal of Cardiology**, May 1994, Vol. 10, No. 4, p.p. 413-421

Study of diagnostic and angioplasty catheter reuse. Concluded that catheters can be reused without posing a significant threat to patients or staff when cleaning, sterilizing and quality control procedures are followed. Found savings of \$5,000 (Canadian) for each diagnostic catheter reused five times and \$100,000 (Canadian) for each angioplasty catheter that was reused three times.

M.G. Bourassa, M.D., "Is Reuse of Coronary Angioplasty Catheters Safe and Effective?" **Journal of the American College of Cardiology**, November 15, 1994, Vol. 24, No. 6, p.p. 1482-1483

Found that the reuse of catheters resulted in important cost savings in an era of cost restrictions and containment. Recommends that hospitals practicing reuse have in place clear policies regarding catheter reuse. Also recommends that hospitals have standardized cleaning, sterilization and quality control procedures.

E.A. Aton, M.S., et. al., "Safety of Reusing Cardiac Electrophysiology Catheters," **The American Journal of Cardiology**, December 1, 1994, Vol. 74

Author found that electrode catheters could maintain their functionality after being reprocessed. Found that the catheters reprocessed using the Clinical Electrophysiology Laboratory at Barnes Hospital's reusage protocol had residual levels of ethylene oxide concentrations that exceeded the FDA's allowable levels. However, authors notes that the original device manufacturers eliminated this problem by extending aeration cycle or by defining the post sterilization interval to decrease levels of ethylene oxide. Recommends that laboratories reusing electrode catheters establish and implement a validation protocol for their catheter reprocessing.

1993

B. Avitall, M.D., et. al., "Repeated Use of Ablation Catheters: A Prospective Study," **Journal of American College of Cardiology**, November 1, 1993, Vol. 22, No.5, p.p. 1367-1372

Study of Ablation Catheters from a single manufacturer, Webster/Mansfield. Found that the Webster/Mansfield catheters could be reused an average of five times. Avitall wrote that, "clinical follow-up states that reuse of ablation catheters has yet to result in any adverse consequences to the patient." Avital also found no complications resulting from the accumulation of ethylene oxide residues on the device after multiple resterilizations. The total cost savings for reusing ablation catheters in this study was \$128,133 for the 336 procedures performed. It was recommended that each catheter be carefully examined after each use to determine if it can be reprocessed and that validated cleaning, sterilization and functionality testing be in place for reprocessing of catheters.

1990

P. Bentolila, R. Jacob, F. Roberge, "Effects of Re-Use on the Physical Characteristics of Angiographic Catheters," **Journal of Medical Engineering and Technology**, November/December 1990, Vol. 14, No. 6, p.p. 254-259

Bentolila, Jacob and Roberge studied five types of angiographic catheters that were used at the radiological and haemodynamic clinical practice of Sacré-Coeur Hospital in Montreal. The devices were studied for mechanical sturdiness, and for the possibility that reuse of these catheters could be associated with blood contamination by loose particles. The study tested both new and reprocessed catheters, which had been used up to ten times. The doctors found no adverse effects on the maximum tensile strength and elongation at break of the reused catheters. There were some findings of biological debris on the reused catheters; however, the debris was fixed to the lumen surface and the doctors thought the chance of it being carried into the blood stream was unlikely. It is worth noting that the new unused catheters exhibited a significantly higher loose particle count than the reprocessed devices. Therefore, the authors concluded that properly handled reprocessed angiographic catheters are as safe for the patient as new catheters.

1988

S. O' Donoghue, E. Platia. "Reuse of Pacing Catheters: A Survey of Safety and Efficacy." **PACE**, September 1988, Vol. 11, p.p. 1279-1280

This study focused on the occurrences of superficial skin infections or bacteremia associated with new and reprocessed devices used in electrophysiologic studies (non-lumen, woven Dacron, multi-electrode pacing catheters). Found that the rates of infection were extremely low, with no significant variance between the reused group and the new group. Article states that the devices are sufficiently durable to allow them to be reused in excess of five times and that single-use appears to be an unnecessary and expensive policy.

1987

Dunnigan, M.D., et. al., "Success of Re-Use of Cardiac Electrode Catheters," **American Journal of Cardiology**, October 1, 1987, Vol. 60, p.p. 807-810

This five-year study of cardiac electrode catheter reuse occurred from 1981 to 1986, during which time 178 catheters were used 1,526 times for 847 electrophysiologic procedures with detailed records kept of the devices' use and testing. There were no complications due to reuse during the five-year study. All 178 catheters functioned for cardiac pacing and electrographic recording and the surveillance cultures and biologic indicators showed that adequate sterilization methods and procedures were used. The study concluded that electrode catheters may be safely reused as long as a thorough cleaning, testing and record keeping system is in place. Reuse potentially reduced the cost of the electrophysiologic catheterization to \$30 per use, versus \$200 per use for the single-use device.

ATTACHMENT H

MAUDE Search

BRAND NAME	DEFLECTABLE ORTHOGONAL CATHETER
TYPE OF DEVICE	SEE ABOVE
MANUFACTURER	PARAGON HEALTHCARE CORP. 107 CORPORATE DR. SPARTANBURG, SC 29303 US 209533 216005 202692 1062310-1999-00001 DQO MANUFACTURER
DEVICE EVENT KEY	YES
MDR REPORT KEY	1
EVENT KEY	1
→ REPORT NUMBER	11-MAR-1999
PRODUCT CODE	NO
REPORT SOURCE	YES
WAS MANUFACTURER REPORT SUBMITTED?	ELECTRODE DETACHED & LODGED IN PATIENT
NUMBER OF DEVICES IN EVENT	HEALTH PROFESSIONAL
NUMBER OF PATIENTS INVOLVED	7FR D-TYPE
DATE FDA RECEIVED	0D7-8X2D-005-FS
IS THIS AN ADVERSE EVENT REPORT?	ORIGINAL LOT 708492-599
IS THIS A PRODUCT PROBLEM REPORT?	PARAGON LOT 9900008
OUTCOME OF EVENT	YES
DEVICE OPERATOR	3. ABLATION CATHETER.ER, 2. HEXAPOLAR CATHETER,
DEVICE MODEL NUMBER	YES
DEVICE CATALOGUE NUMBER	FOLLOWUP
DEVICE LOT NUMBER	10-Mar-1999
OTHER DEVICE ID NUMBER	NO
WAS DEVICE AVAILABLE FOR EVALUATION?	USER FACILITY
CONCOMITANT MEDICAL PRODUCTS	28-JAN-1999
IS THE REPORTER A HEALTH PROFESSIONAL?	1062310-1999-00001
TYPE OF REPORT	OTHER
REPORT DATE	
WAS THE REPORT SENT TO FDA?	
INITIAL REPORT SOURCE	
DATE MANUFACTURER RECEIVED	
MANUFACTURER REPORT NO	
EVENT REPORT TYPE	

WAS DEVICE EVALUATED BY MANUFACTURER?	YES
MANUFACTURE DEVICE DATE	*(error)
LABELED FOR SINGLE USE?	NO
REMEDIAL ACTION	OTHER
TYPE OF DEVICE USAGE	REUSE
BASELINE BRAND NAME	DEFLECTABLE ORTHOGONAL CATHETER
BASELINE GENERIC NAME	SEE ABOVE
BASELINE CATALOGUE NUMBER	OD7-8XLD-005-FS
BASELINE MODEL NUMBER	7FR D-TYPE
OTHER BASELINE ID NUMBER	PARAGON LOT 9900008

EVENT DESCRIPTION

PER PHONE COMMUNICATION FROM HOSP, A CORDIS WEBSTER ORTHOGONAL ELECTROPHYSIOLOGY CATHETER WAS USED IN AN ELECTROPHYSIOLOGY STUDY THAT PROGRESSED WITHOUT DIFFICULTY UNTIL THE PHYSICIAN REMOVED THE CATHETER FROM THE CORONARY SINUS. THE PHYSICIAN REPORTED RESISTANCE UPON REMOVAL FROM CORONARY SINUS. PT WAS NONSYMPTOMATIC THROUGHOUT PROCEDURE. A CHEST FILM CONFIRMED THAT A SMALL FRAGMENT WAS IMBEDDED IN THE RIGHT ATRIAL WALL. SURGICAL CONSULT REVEALED THAT REMOVAL OF FRAGMENT WAS/IS NOT INDICATED. PT REMAINS SYMPTOM FREE PER HOSP REPORT. FRAGMENT PRESUMABLY IS A SINGLE PLATINUM ELECTRODE FROM CATHETER. ONE OF THE SURFACE MOUNTED ELECTRODES MAY HAVE BEEN COMPROMISED BY THE EXTERIOR RIM OF A TUBE USED TO PACKAGE THE CATHETER INSIDE THE MYLAR TYVEK POUCH.

ADDITIONAL MANUFACTURER NARRATIVE

ON MARCH 8, 1999, PARAGON REC'D A COPY OF A MDR FILED BY WESLEY MED CTR IN WICHITA, KANSAS. THE MDR REPORTED THE PERFORMANCE OF THE DEVICE DURING A PERCUTANEOUS INTERVENTIONAL ELECTROPHYSIOLOGY STUDY. THE USER FACILITY INFORMED PARAGON THAT THE ELECTROPHYSIOLOGY STUDY PROCEEDED WITHOUT DIFFICULTY UNTIL THE PHYSICIAN INITIATED THE REMOVAL OF THE CATHETER FROM THE PT'S CORONARY SINUS. THE PT WAS DESCRIBED BY A CLINICIAN TO BE ASYMPTOMATIC DURING AND POST ELECTROPHYSIOLOGY PROCEDURE. A CHEST FILM ORDERED BY THE ELECTROPHYSIOLOGIST CONFIRMED THE LOCATION OF A METAL FRAGMENT IN THE RIGHT ATRIAL WALL. CONSULTATION WITH A CARDIO-THORACIC SURGEON REPORTEDLY DETERMINED THAT NO INTERVENTION WAS INDICATED. PARAGON IS UNAWARE OF ANY ADVERSE EFFECTS TO THE PT OR THAT ANY FURTHER CORRECTIVE PROCEDURE WAS RECOMMENDED. NO OTHER ADVERSE EVENTS HAVE BEEN REPORTED TO PARAGON. THE CO'S INVESTIGATIVE ANALYSIS HAS DEMONSTRATED THAT ANY POSSIBLE RECURRENCE OF THIS INCIDENT WOULD BE LIMITED TO THIS TYPE OF CATHETER. THE PRODUCT CONTAINED SURFACE-MOUNTED PLATINUM ELECTRODES. THEY MAY HAVE COME IN CONTACT WITH THE EXTERIOR RIM OF THE TUBING WHILE BEING INSERTED. THIS MANEUVER MAY HAVE COMPROMISED THE STABILITY OF THE CATHETER ELECTRODES IN ISOLATED CASES. IF ALL ELECTRODES ARE FOUND TO BE PROPERLY INTACT, FOLLOWING INSPECTION, THEY WILL BE REPACKAGED INTO MYLAR TYVEK POUCHES WITHOUT TUBES AND RETURNED TO THEIR OWNERS. COMPROMISED, OR QUESTIONABLE, UNITS WILL BE DESTROYED AND REPLACED WITH NEW EQUIPMENT. RECORDS OF THESE INSPECTIONS WILL BE ADDED TO DETAILED REPROCESSING HISTORIES ON FILE AT PARAGON.

ATTACHMENT I

BRAND NAME	MAP
MANUFACTURER	EPT, A DIV. OF BSC 2710 ORCHARD PARKWAY SAN JOSE, CA 95134-2012 US 163382 167912 157793 6000087-1998-00002 DRF MANUFACTURER YES 1 1 15-MAY-1998 YES NO MALFUNCTION UNK 1675P 7B296 YES UNK NO INITIAL 17-Apr-1998 NO UNK HOSPITAL UNK HEALTH PROFESSIONAL UNK 6000087-1998-00002 MALFUNCTION YES 01-FEB-1997 NO OTHER INITIAL MAP *
DEVICE EVENT KEY	
MDR REPORT KEY	
EVENT KEY	
→ REPORT NUMBER	
PRODUCT CODE	
REPORT SOURCE	
WAS MANUFACTURER REPORT SUBMITTED?	
NUMBER OF DEVICES IN EVENT	
NUMBER OF PATIENTS INVOLVED	
DATE FDA RECEIVED	
IS THIS AN ADVERSE EVENT REPORT?	
IS THIS A PRODUCT PROBLEM REPORT?	
OUTCOME OF EVENT	
DEVICE EXPIRATION DATE	
DEVICE MODEL NUMBER	
DEVICE LOT NUMBER	
WAS DEVICE AVAILABLE FOR EVALUATION?	
CONCOMITANT MEDICAL PRODUCTS	
IS THE REPORTER A HEALTH PROFESSIONAL?	
TYPE OF REPORT	
REPORT DATE	
WAS THE REPORT SENT TO FDA?	
DATE REPORT SENT TO FDA	
EVENT LOCATION	
DATE REPORT TO MANUFACTURER	
INITIAL REPORT SOURCE	
DATE MANUFACTURER RECEIVED	
MANUFACTURER REPORT NO	
EVENT REPORT TYPE	
WAS DEVICE EVALUATED BY MANUFACTURER?	
MANUFACTURE DEVICE DATE	
LABELED FOR SINGLE USE?	
REMEDIAL ACTION	
TYPE OF DEVICE USAGE	
BASELINE BRAND NAME	
BASELINE GENERIC NAME	

BASELINE CATALOGUE NUMBER *
BASELINE MODEL NUMBER 1675P
OTHER BASELINE ID NUMBER *
EVENT DESCRIPTION

SMALL SECTION OF DISTAL TIP IN PROXIMITY TO ELECTRODE SIDE OF CATHETER
BROKE AWAY. UNABLE TO LOCATE FRAGMENT.

ADDITIONAL MANUFACTURER NARRATIVE

THIS MEDICAL DEVICE REPORT IS NOT AN ADMISSION BY EPT, A DIV. OF BSC, THAT ANY PRODUCT DESIGN MFG OR SOLD BY SAID COMPANY, CAUSED OR CONTRIBUTED TO ANY OF THE EVENTS DESCRIBED IN THIS REPORT, NOR THAT EPT, A DIV. OF BSC HAS LEGAL LIABILITY OR RESPONSIBILITY WITH RESPECT TO SUCH EVENTS OR OCCURRENCES OR THAT INFO CONTAINED IN THIS REPORT IS REQUIRED TO BE REPORTED UNDER MDR REGULATIONS. F-1 THROUGH F.14: THIS INFO WAS NOT PROVIDED BY THE HOSPITAL REFERENCED IN F.3. IT WAS COMPLETED BY BSC SAN JOSE COMPLAINT COORDINATOR TO THE BEST OF HER KNOWLEDGE BASED ON INFO PROVIDED BY SALES REP.

[\[Return to Search\]](#)

[\[CDRH HomePage\]](#)

[\[FDA HomePage\]](#)

[\[Comments\]](#)

(Database Updated July 6, 1999)

BRAND NAME	DEFLECTIBLE D-CURVE ABLATION CATHETER
TYPE OF DEVICE	CATHETER
MANUFACTURER	CORDIS WEBSTER, INC. 4750 LITTLEJOHN ST BALDWIN PARK, CA 91706 US
DEVICE EVENT KEY	30352
MDR REPORT KEY	29314
EVENT KEY	27472
REPORT NUMBER	4501350000-1995-0088
PRODUCT CODE	LPB
REPORT SOURCE	USER FACILITY
WAS MANUFACTURER REPORT SUBMITTED?	NO
NUMBER OF DEVICES IN EVENT	1
NUMBER OF PATIENTS INVOLVED	1
DATE FDA RECEIVED	04-DEC-1995
IS THIS AN ADVERSE EVENT REPORT?	NO
IS THIS A PRODUCT PROBLEM REPORT?	YES
OUTCOME OF EVENT	HOSPITALIZATION
DATE OF REPORT	04-Dec-1995
DEVICE OPERATOR	HEALTH PROFESSIONAL
DEVICE EXPIRATION DATE	01-DEC-1997
DEVICE LOT NUMBER	411044
WAS DEVICE AVAILABLE FOR EVALUATION?	YES
IS THE REPORTER A HEALTH PROFESSIONAL?	YES
DISTRIBUTOR FACILITY AWARE DATE	22-NOV-1995
TYPE OF REPORT	INITIAL
WAS THE REPORT SENT TO FDA?	YES
DATE REPORT SENT TO FDA	04-DEC-1995
EVENT LOCATION	HOSPITAL
DATE REPORT TO MANUFACTURER	04-DEC-1995
EVENT DESCRIPTION	PT IN CARDIAC CATH LAB FOR ABLATION. CATHETER PRESENT IN RIGHT ATRIUM. WHILE PHYSICIAN WAS REPOSITIONING THE CATHETER UNDER FLUOROSCOPY, CATHETER TIP WAS NOTED TO BE DETACHED FROM CATHETER. PHYSICIAN ATTEMPTED RETRIEVAL; UNABLE TO RETRIEVE. PHYSICIAN CONTACTED MFR WHO STATED THAT PREVIOUS EXPERIENCE INDICATED CATHETER TIP COULD SAFELY BE

LEFT IN CURRENT POSITION (WEDGED INTO CORONARY SINUS). PT KEPT OVERNIGHT FOR OBSERVATION; DISCHARGED HOME FOLLOWING DAY. CATHETER TIP AND APPROXIMATELY 2 MM OF CATHETER TUBING LEFT IN PT. (LABEL)

[\[Return to Search\]](#)

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[\[FDA HomePage\]](#)

[\[Comments\]](#)

(Database Updated July 6, 1999)

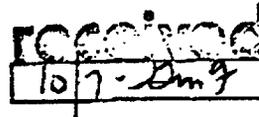
ATTACHMENT J

ATTACHMENT K



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 6 1999



Larry R. Pilot, Esq.
McKenna & Cuneo, L.L.P.
Counsel to Petitioner
Medical Device Manufacturers Association
1900 K Street, N.W.
Washington, D.C. 20006

Re: Docket No.. 99P-1516/CP 1

Dear Mr. Pilot:

This letter is in response to your citizen petition on behalf of the Medical Device Manufacturers Association (MDMA), dated May 20, 1999, requesting that the Food and Drug Administration (FDA) issue a proposed regulation identifying reprocessed single use devices as banned devices and that such proposed regulation be made effective upon its publication in the Federal Register. As stated, the petition applies to practitioners, institutions, and reproprocessors. Thank you for the detailed petition and the issues you raised. We regret the delay in responding.

The petition requests that FDA issue a proposed regulation to ban the practice of reprocessing single use devices and to make the ban effective on the date of publication of the proposed regulation in the Federal Register. The stated grounds for the petition included a statement that the "complexity of these devices for their intended use severely constricts any possibility of cleaning and sterilizing the device in order to restore it to its original unused condition." Your letter also stated that manufacturers are required to obtain PMA approval or 510(k) clearance for their devices and that "FDA required labeling" for such devices must state that they are for single use and are not to be reused. You stated that this requirement must be met in the absence of information provided to FDA demonstrating that reprocessing will not adversely affect product safety or effectiveness.

FDA has carefully reviewed your petition to ban the reprocessing of single use devices, and we are denying it. The Agency does not believe that banning is the appropriate action to address the many and varied issues tied to this practice. Our reasoning follows.

There is no clear evidence that reprocessing presents "an unreasonable and substantial risk of illness or injury," which is one of the criteria for banning a medical device. FDA-

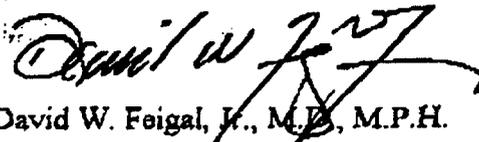
has received adverse event reports where a reprocessed single use device was involved; however, in each of those cases, it was not clear that reprocessing caused the problem reported. In fact, FDA has been unable to find clear evidence of adverse patient outcomes associated with the reuse of a single use device from any source. Therefore, the "unreasonable and substantial risk" criterion has not been met.

According to the banning provision of the Federal Food, Drug and Cosmetic Act, Section 516, another criterion that can be used for taking such an action is substantial deception. As your petition suggests, it would be difficult to establish whether deception with respect to reprocessed devices has occurred and who was the target of that deception. Even if we did establish a basis to claim substantial deception, the statutory option of banning does not seem to be an appropriate response. There is no evidence to date supporting any such danger to individual health from the reuse of products that have been labeled for only a single use. This burden has not been met.

While FDA will not support a banning action, we believe that a significant re-evaluation of FDA's position with regard to the reuse of single use devices is in order. During the May 1999 AAMI/FDA Reuse Conference, FDA committed to provide a formal response to the conference in a Federal Register notice by October 1999. We plan to honor that commitment. Our Federal Register statement will address the direction of FDA's thinking with regard to key issues and concerns raised at the May conference, such as data generation, premarket submissions, and labeling. We encourage you and your client, MDMA, to be active participants in reviewing and responding to the upcoming Federal Register notice and any other document that FDA may issue on this subject.

If you have any questions, please contact Larry Spears at 301-594-4646, Ext. 151.

Sincerely yours,



David W. Feigal, Jr., M.D., M.P.H.
Director
Center for Devices and
Radiological Health

ATTACHMENT L



2919 '98 JUL 15 P1154998

Nancy Singer, Esq.
Special Counsel
Health Industry Manufacturers Association
1200 G Street, N.W., Suite 400
Washington, D.C. 20005

Docket No. 97P-0377

Dear Ms. Singer:

This letter is in response to your citizen petition on behalf of the Health Industry Manufacturers Association (HIMA), dated September 5, 1997, to require commercial ("for profit") reprocessors of disposable medical devices to comply with all applicable FDA regulations governing medical device manufacturing, including premarket notification (510(k)), premarket approval (PMA), medical device reporting (MDR), device labeling, good manufacturing practices (GMPs), establishment registration, and device listing. The petition states that it does not apply to reprocessors of disposable hemodialyzers or end-user facilities, i.e., hospitals, clinics, etc. A response to the HIMA petition, filed in the Dockets Management Branch by the Association for Medical Device Reprocessors (AMDR), will also be addressed in this letter. Thank you for the detailed petition and the important issues you raised. We regret the delay in responding.

The petition requests that commercial reprocessors be required to comply with the GMPs. This is already the case. These reprocessors are inspected in accordance with the current Quality System regulation, Title 21, Code of Federal Regulations (CFR), Part 820 and they are subject to the labeling requirements of 21 CFR Part 801. This has been FDA's position for some time, as evidenced in a December 27, 1995, letter to trade associations from Lillian Gill, Director, Office of Compliance, CDRH. The letter states that "any person or firm that reprocesses medical devices for health care facilities and engages in repackaging, relabeling, or sterilization activities (including any associated processing operations, e.g., cleaning) are required to comply with the Good Manufacturing Practice (GMP) and device labeling requirements of the Federal regulations, 21 CFR Parts 820 and 801, respectively." In fact, FDA has considered such reprocessing firms to be manufacturers under the GMP regulations promulgated in 1978 and continues to consider them as such under the Quality System regulation which became effective in June 1997 (with a special 1 year transition period for design control compliance). Inspections have been conducted of several such facilities and follow-up regulatory action has been taken, as

97P-0377

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appropriate, including the issuance of Warning Letters. Assignments to inspect previously uninspected reprocessors will also be issued.

FDA believes that reprocessors' and original equipment manufacturers' (OEMs') compliance with GMP requirements provides an appropriate measure of public health protection for patients and health care providers by ensuring sufficient control over the individual firm's manufacturing and quality assurance operations. These requirements provide a reasonable assurance that the firm is providing devices that meet appropriate specifications for safety and performance. In addition, reprocessors are also subject to medical device reporting, registration, and listing requirements. FDA notes the current general absence of evidence of adverse patient outcomes attributed to the reuse of single-use devices.

The Association of Medical Device Reprocessors (AMDR) submitted a March 12, 1998, response to the HIMA citizen petition requesting denial of that petition, while raising legal questions of FDA's statutory authority to require device marketing clearance for reprocessing devices. Our reply to your petition will not respond to AMDR's legal argument except to note that FDA's regulatory approach is not based on their legal position. Rather, FDA will continue to rely on labeling and existing postmarket requirements, which include relevant GMP requirements, medical device reporting, registration and listing, and labeling.

FDA is very interested in learning the effects that reprocessed devices have on patients. An FDA laboratory project is currently evaluating the effects that various cleaning agents have on device performance, and the material composition of used balloon angioplasty catheters. This project aims to establish how the reprocessing of the used devices could affect device utility. Additionally, we are encouraging trade and scientific organizations, OEMs, user facilities, and others, to provide any data demonstrating adverse patient outcomes from the use of reprocessed "single use only" devices. We encourage HIMA to provide any such data to FDA for our review. To date, FDA has seen no documented evidence that the treatment of patients with, or other patient use of, these reprocessed devices has caused adverse clinical outcomes.

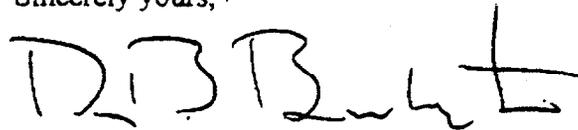
Finally, FDA published an Advanced Notice of Proposed Rulemaking (ANPRM) in the Federal Register of December 23, 1997 (62 FR 67011), regarding device refurbishers, reconditioners, servicers, and as-is remarketers. The public comment period was extended to June 29, 1998. The ANPRM focuses primarily on capital equipment; however, the ANPRM may be used as a venue to provide an opportunity to comment on FDA's regulation of reprocessed single-use devices.

Page 3 - Ms. Nancy Singer

Until the agency has an opportunity to review and evaluate any comments concerning this issue, it is premature for the agency to make any decision regarding a change in FDA's regulatory position.

Once again, we appreciate receiving your citizen petition on this most important subject. If you have any questions, please contact Mr. Larry Spears at 301-594-4646, Ext. 151.

Sincerely yours,

A handwritten signature in black ink, appearing to read "D. B. Burlington". The signature is written in a cursive, somewhat stylized font.

D. Bruce Burlington, M.D.
Director
Center for Devices and
Radiological Health

ATTACHMENT M

FDA's Appendix B, Attachment 2 Device Information: Cardiac Guidewire
FDA's Risk Category: High

The following device information is taken from the online CDRH Product Code Classification Database:

Device: WIRE, GUIDE CATHETER

Medical Specialty: Cardiovascular

Product code: DQX

Device Class: 2

510(K) Exempt: No

Regulation Number: 870.1330

Identification: A catheter guide wire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel.

Flowchart 1 – Infection Risk:

- 1.) *Question: Is the SUD a non-critical device? AMDR Answer: No – Under the “Spaulding” definition of device criticality, the guide catheter wire engages the vascular system, meaning it enters the bloodstream.*
- 2.) *Question: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed? AMDR Answer: No – AMDR companies know of no postmarket information that suggests that proper reprocessing of guide catheter wires presents an increased risk of infection*.*
- 3.) *Question: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection? AMDR Answer: Yes.*
- 4.) *Question: Does a reusable device exist that has an equivalent design and the same intended use as the SUD? AMDR Answer: No – To the best of AMDR’s knowledge, a reusable counterpart does not exist.*
- 5.) *Question: Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the SUD has been adequately cleaned and disinfected/sterilized? AMDR Answer: Yes – The AAMI/ANSI ST35-1996 is an FDA recognized standard for cleaning and sterilization.*

AMDR Conclusion: Moderate Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) *Question: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed? AMDR Answer: No – AMDR companies know of no postmarket information that suggests that proper reprocessing of a guide catheter wire poses an increased risk of injury*.*
- 2.) *Question: Could failure of the device cause death, serious injury or permanent impairment? AMDR Answer: Yes – The failure of a guide catheter wire - new or reprocessed - could potentially cause death, serious injury or permanent impairment.*
- 3.) *Question: Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected? AMDR Answer: No – While the materials, coatings or components of guide catheter wires are sometimes altered during their first use, AMDR members do not reprocess damaged guide catheter wires. Indeed, a guide catheter wire whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely*

affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess guide catheter wires with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any guide catheter wire is reprocessed. Every guide catheter wire reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the guide catheter wire is rejected and is not returned to the hospital that had requested reprocessing.

- 2a.) *Question: Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use? AMDR Answer: No.*
- 2b.) *Question: Can visual inspection determine if performance has been affected? AMDR Answer: Yes – AMDR companies visually inspect every guide catheter wire. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the guide catheter wire, it is rejected and not returned to the hospital that had requested reprocessing.*

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)? No – Not an implant*
- 2.) *What is the risk of infection according to Flowchart 1? Moderate Risk*
- 3.) *What is the risk of inadequate performance according to Flowchart 2? Low Risk*
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk. Yes – Moderate Risk*
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2? No*

AMDR's Risk Categorization: MODERATE RISK
--

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of guide catheter wires be made public.

**Appendix B, Attachment 2 Device Information: Percutaneous Transluminal Coronary Angioplasty (PTCA)
Catheter
FDA's Risk Category: High**

The following device information is taken from the online CDRH Product Code Classification Database:

**Device: CATHETERS, TRANSLUMINAL CORONARY ANGIOPLASTY,
PERCUTANEOUS & OPERATIVE**

Medical Specialty: Cardiovascular
Product code: LOX
Device Class: 3
510(K) Exempt: No
Regulation Number: None Available
Identification: None Available

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the percutaneous and operative transluminal coronary angioplasty catheter engages the vascular system, meaning it enters the bloodstream.

- 1.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – There is substantial postmarket information that supports the safety of proper reprocessing of percutaneous and operative transluminal coronary angioplasty catheters*. See, for example:
Browne, K.F., Maldonado, R., Telatnick, M., Blietstra, R.E., Brenner, A.S., “*Initial Experience with Reuse of Coronary Angioplasty Catheters in the United States,*” **The American College of Cardiology**, December 1997, Vol. 30, No. 7, 1735-1740.
Power, K.A., “*Abstraction: Catheter-based coronary and valvular interventions (PTCA, atherectomy, laser, valvuloplasty),*” **American Heart Association**, Abstract Submission for 1999.

- 2.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: Yes.**

- 3.) **Question:** *Does a reusable device exist that has an equivalent design and the same intended as the SUD?* **AMDR Answer: No** – To the best of AMDR’s knowledge, percutaneous and operative transluminal coronary angioplasty catheters are marketed exclusively as “single-use only.”

- 4.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the SUD has been adequately cleaned and disinfected/sterilized?* **AMDR Answer: Yes** – There is both a CDRH guidance document (Office of Device Evaluation, Division of Cardiovascular, Respiratory and Neurological Devices, Interventional Cardiology Devices Group, “Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents” (May 1995)) and an FDA recognized standard for cleaning and sterilization (AAMI/ANSI ST35-1996).

AMDR Conclusion: Moderate Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – There is substantial postmarket information that supports the safety of proper reprocessing of percutaneous and operative transluminal coronary angioplasty catheters*. (See examples cited in Flowchart 1.)

- 2.) **Question:** *Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer:** Yes – The failure of a percutaneous and operative transluminal coronary angioplasty catheter - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) **Question:** *Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer:** No – While the materials, coatings or components of percutaneous and operative transluminal coronary angioplasty catheters are sometimes altered during their first use, AMDR members do not reprocess damaged percutaneous and operative transluminal coronary angioplasty catheters. Indeed, a percutaneous and operative transluminal coronary angioplasty catheter whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess percutaneous and operative transluminal coronary angioplasty catheters with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any percutaneous and operative transluminal coronary angioplasty catheter is reprocessed. Every percutaneous and operative transluminal coronary angioplasty catheter reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the percutaneous and operative transluminal coronary angioplasty catheter is rejected and is not returned to the hospital that had requested reprocessing.

2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer:** Yes – There is a CDRH guidance document (Office of Device Evaluation, Division of Cardiovascular, Respiratory and Neurological Devices, Interventional Cardiology Devices Group, "Guidance for the Submission of Research and Marketing Applications for Interventional Cardiology Devices: PTCA Catheters, Atherectomy Catheters, Lasers, Intravascular Stents" (May 1995)).

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* No – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* Moderate Risk
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* Low Risk
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* Yes – Moderate Risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* No

AMDR's Risk Categorization: MODERATE RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of percutaneous and operative transluminal coronary angioplasty catheters be made public.

FDA's Appendix B, Attachment 2 Device Information: Phacoemulsification Needle
FDA's Risk Category: High

The following device information is taken from the online CDRH Product Code Classification Database:

Device: FLUIDIC, PHACOEMULSIFICATION/PHACOFRAGMENTATION

Medical Specialty: Ophthalmic

Product code: MUS

Device Class: 2

510(K) Exempt: No

Regulation Number: 886.4670

Identification: *A phacofragmentation system is an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract.*

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the fluidic phacoemulsification/phacofragmentation device engages mucus membrane.
- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of fluidic phacoemulsification/phacofragmentation devices presents an increased risk of infection*.
- 3.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: Yes**
- 4.) **Question:** *Does a reusable device exist that has an equivalent design and the same intended use as the SUD?* **AMDR Answer: No** – To the best of AMDR’s knowledge, fluidic phacoemulsification/phacofragmentation devices are marketed exclusively as “single use only.”
- 5.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM, or a CDRH guidance document that may be used to determine if the SUD has been adequately cleaned and disinfected/sterilized?* **AMDR Answer: Yes** – The AAMI/ANSI ST35-1996 is an FDA recognized standard for cleaning and sterilization.

AMDR Conclusion: Moderate Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of a fluidic phacoemulsification/phacofragmentation device poses an increased risk of injury*.
- 2.) **Question:** *Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer: Yes** – The failure of a fluidic phacoemulsification/phacofragmentation device - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) **Question:** *Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer: No** – While the materials, coatings or components of fluidic phacoemulsification/phacofragmentation devices are sometimes altered during their first use, AMDR

members do not reprocess damaged fluidic phacoemulsification/phacofragmentation devices. Indeed, a fluidic phacoemulsification/phacofragmentation device whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess fluidic phacoemulsification/phacofragmentation devices with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any fluidic phacoemulsification/phacofragmentation device is reprocessed. Every fluidic phacoemulsification/phacofragmentation device reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the fluidic phacoemulsification/phacofragmentation device is rejected and is not returned to the hospital that had requested reprocessing.

- 2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer:** No.
- 2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer:** Yes – AMDR companies visually inspect every fluidic phacoemulsification/phacofragmentation device. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the fluidic phacoemulsification/phacofragmentation device, it is rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* No – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* Moderate Risk
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* Low Risk
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* Yes – Moderate Risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* No

AMDR's Risk Categorization: MODERATE RISK
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* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of fluidic phacoemulsification/phacofragmentation devices be made public.

FDA's Appendix B, Attachment 2 Device Information: Biopsy forceps
FDA's Risk Category: High

The following device information is taken from the online CDRH Product Code Classification Database:

Device: FORCEPS, BIOPSY, BRONCHOSCOPE (NON-RIGID)

Medical Specialty: Ear, Nose and Throat

Product code: BWH

Device Class: 2

510(K) Exempt: No

Regulation Number: 874.4680

Identification: A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the bronchoscope and is intended to examine or treat the larynx and tracheobronchial tree. It is typically used with a fiberoptic light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the rigid ventilating bronchoscope, rigid nonventilating bronchoscope, nonrigid bronchoscope, laryngeal-bronchial telescope, flexible foreign body claw, bronchoscope tubing, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, flexible biopsy curette, and rigid bronchoscope aspirating tube, but excludes the fiberoptic light source and carrier.

Flowchart 1 – Infection Risk:

- 1.) *Question: Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the non-rigid bronchoscope biopsy forceps may engage the vascular system.
- 2.) *Question: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of non-rigid bronchoscope biopsy forceps presents an increased risk of infection*.
- 3.) *Question: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: Yes.**
- 4.) *Question: Does a reusable device exist that has an equivalent design and the same intended as the SUD?* **AMDR Answer: Yes** – Reusable counterparts exist:

Manufacturer	Model – Cat #	Description	Size
Olympus	FB-44D-51125	Std. Elipsoid Biopsy Forceps	1.2mm

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) *Question: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of non-rigid bronchoscope biopsy forceps presents an increased risk of injury*.
- 2.) *Question: Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer: Yes** – The failure of a non-rigid bronchoscope biopsy forceps - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) *Question: Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer: No** – While the materials, coatings or components of non-rigid bronchoscope biopsy forceps are sometimes altered during their first use, AMDR members do not reprocess damaged non-rigid bronchoscope biopsy forceps. Indeed, non-rigid bronchoscope biopsy forceps whose materials, coatings or components have been damaged or altered by a single use in such a way that

the performance of the device has been adversely affected would not be suitable candidates for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess non-rigid bronchoscope biopsy forceps with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before non-rigid bronchoscope biopsy forceps are reprocessed. All non-rigid bronchoscope biopsy forceps reprocessed by AMDR companies are tested for functionality and are examined under high magnification for any signs of wear or damage. If a problem is detected, the non-rigid bronchoscope biopsy forceps are rejected and are not returned to the hospital that had requested reprocessing.

- 2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer:** No.
- 2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer:** Yes – AMDR companies visually inspect every non-rigid bronchoscope biopsy forceps. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the non-rigid bronchoscope biopsy forceps, they are rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* No – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* Low Risk
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* Low Risk
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* No – Low Risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* Yes – Low Risk

AMDR's Risk Categorization: LOW RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of non-rigid bronchoscope biopsy forceps be made public.

**FDA's Appendix B, Attachment 2 Device Information: Angiography Catheter
FDA's Risk Category: High**

The following device information is taken from the online CDRH Product Code Classification Database:

Device: CATHETER, INTRAVASCULAR, DIAGNOSTIC

Medical Specialty: Cardiovascular

Product Code: DQO

Device Class: 2

510(k) Exempt : No

Regulation Number: 870.1200

Identification: An intravascular diagnostic catheter is a device used to record intracardiac pressures, to sample blood, and to introduce substances into the heart and vessels. Included in this generic device are right-heart catheters, left-heart catheters and angiographic catheters, among others.

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the intravascular diagnostic catheter engages the vascular system, meaning it enters the bloodstream.
- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of intravascular diagnostic catheters presents an increased risk of infection*.
- 3.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: No** – An intravascular diagnostic catheter is a sealed lumen device that is reprocessed regularly by AMDR companies without any cleaning difficulties.

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of intravascular diagnostic catheters presents an increased risk of injury*.
- 2.) **Question:** *Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer: Yes** – The failure of an intravascular diagnostic catheter - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) **Question:** *Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer: No** – While the materials, coatings or components of intravascular diagnostic catheters are sometimes altered during their first use, AMDR members do not reprocess damaged intravascular diagnostic catheters. Indeed, an intravascular diagnostic catheter whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess intravascular diagnostic catheters with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any intravascular diagnostic catheter is reprocessed. Every intravascular diagnostic catheter reprocessed by AMDR companies is tested for functionality and is examined under high

magnification for any signs of wear or damage. If a problem is detected, the intravascular diagnostic catheter is rejected and is not returned to the hospital that had requested reprocessing.

2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer:** No.

2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer:** Yes – AMDR companies visually inspect every intravascular diagnostic catheter. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the intravascular diagnostic catheter, it is rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* No – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* Low Risk
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* Low Risk
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* No – Low risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* Yes – Low Risk

AMDR's Risk Categorization: LOW RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of intravascular diagnostic catheters be made public.

FDA's Appendix B, Attachment 2 Device Information: Needle
FDA's Risk Category: High

The following device information is taken from the online CDRH Product Code Classification Database:

Device: TROCAR

Medical Specialty: Cardiovascular

Product code: DRC

Device Class: 2

510(K) Exempt: No

Regulation Number: 870.1390

Identification: A trocar is a sharp-pointed instrument used with a cannula for piercing a vessel or chamber to facilitate insertion of the cannula.

Flowchart 1 – Infection Risk:

- 1.) *Question: Is the SUD a non-critical device? AMDR Answer: No* – Under the “Spaulding” definition of device criticality, the trocar engages the vascular system.
- 2.) *Question: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed? AMDR Answer: No* – AMDR companies know of no postmarket information that suggests that proper reprocessing of trocars presents an increased risk of infection*.
- 3.) *Question: Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection? AMDR Answer: Yes.*
- 4.) *Question: Does a reusable device exist that has an equivalent design and the same intended use as the SUD? AMDR Answer: Yes* – Reusable counterparts exist:

Manufacturer	Model – Cat #	Description	Size
Codman	51-8000	KARP Aortic Punch	4mm
Codman	51-8001	KARP Aortic Punch	5mm
Codman	51-8006	SWEET Sternal Punch	9 ½” (241mm)

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) *Question: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed? AMDR Answer: No* – AMDR companies know of no postmarket information that suggests that proper reprocessing of trocars presents an increased risk of injury*.
- 2.) *Question: Could failure of the device cause death, serious injury or permanent impairment? AMDR Answer: Yes* – The failure of a trocar - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) *Question: Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected? AMDR Answer: No* – While the materials, coatings or components of trocars are sometimes altered during their first use, AMDR members do not reprocess damaged trocars. Indeed, a trocar whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to

reprocess trocars with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any trocar is reprocessed. Every trocar reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the trocar is rejected and is not returned to the hospital that had requested reprocessing.

- 2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer: No.**
- 2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer: Yes** – AMDR companies visually inspect every trocar. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the trocar, it is rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* **No** – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* **Low Risk**
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* **Low Risk**
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* **No** – Low risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* **Yes** – Low Risk

AMDR's Risk Categorization: LOW RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of trocars be made public.

**Appendix B, Attachment 2 Device Information: Electrophysiology Recording Catheter
FDA's Risk Category: High**

The following device information is taken from the online CDRH Product Code Classification Database:

Device: CATHETER, ELECTRODE RECORDING, OR PROBE, ELECTRODE RECORDING

Medical Specialty: Cardiovascular

Product code: DRF

Device Class: 2

510(K) Exempt: No

Regulation Number: 870.1220*

Identification: An electrode recording catheter or an electrode recording probe is a device used to detect an intracardiac electrocardiogram, or to detect cardiac output or left-to-right heart shunts. The device may be unipolar or multipolar for electrocardiogram detection, or may be a platinum-tipped catheter that senses the presence of a special indicator for cardiac output or left-to-right heart shunt determination.

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the electrode recording catheter or electrode recording probe engages the vascular system, meaning it enters the bloodstream.

- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – There is substantial postmarket information that supports the safety of proper reprocessing of the electrode recording catheter and the electrode recording probe**. See, for example:
Aton, EA, Murray, P, Frase, V, Conaway, L, Cain, ME, “*Safety of Reusing Cardiac Electrophysiology Catheters: A Prospective Study*,” **American Journal of Cardiology**, 1994, 74: 1173-1175
Avitall, B, Kahn, M, Drum, D, Jazayeri, M, Hare, J, “*Repeated Use of Ablation Catheters: A Prospective Study*,” **Journal of the American College of Cardiology**, 1993, 22: 1367-1372
Dunnigan, A, Roberts, C, McNamara, M, Benson, DW, Benditt, DG, “*Success of Re-Use of Cardiac Electrode Catheters*,” **American Journal of Cardiology**, 1987, 60: 807-810
Ferrell, M, Wolf, CE, Ellenbogen, KA, Wood, MA, Clemo, HF, Gilligan, DM, “*Ethylene oxide on electrophysiology catheters following resterilization: implications for catheter reuse*,” **American Journal of Cardiology**, 1997, 80: 1558-1561
O'Donoghue, S, Platia, EV, “*Reuse of Pacing Catheters: A Survey of Safety and Efficacy*,” **Pacing and Clinical Electrophysiology**, 1988, 11: 1279-1280

- 3.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: No** – An electrode recording catheter or electrode recording probe is a sealed lumen device that is reprocessed regularly by AMDR companies without any cleaning difficulties.

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – Postmarket information suggests that proper reprocessing of an electrode recording catheter or electrode recording probe poses no increased risk of injury (see articles listed in Flowchart 1)**.

- 2.) **Question:** *Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer: Yes** – The failure of an electrode recording catheter or electrode recording probe - new or reprocessed - could potentially cause death, serious injury or permanent impairment.

- 3.) **Question:** *Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or reesterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer:** No – While the materials, coatings or components of electrode recording catheters or electrode recording probes are sometimes altered during their first use, AMDR members do not reprocess damaged electrode recording catheters or electrode recording probes. Indeed, an electrode recording catheter or electrode recording probe whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess electrode recording catheters or electrode recording probes with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any electrode recording catheter or electrode recording probe is reprocessed. Every electrode recording catheter or electrode recording probe reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the electrode recording catheter or electrode recording probe is rejected and is not returned to the hospital that had requested reprocessing.
- 2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer:** No.
- 2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer:** Yes – AMDR companies visually inspect every electrode recording catheter or electrode recording probe. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the electrode recording catheter or electrode recording probe, it is rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* No – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* Low Risk
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* Low Risk
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* No – Low Risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* Yes – Low Risk

AMDR's Risk Categorization: LOW RISK

* In FDA's Appendix 2, Attachment 2, the electrode recording catheter or electrode recording probe's regulation number was incorrectly listed as 870.1120.

** AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of electrode recording catheters or electrode recording probes be made public.

**FDA's Appendix B, Attachment 2 Device Information: Biopsy Needle (FCG)
FDA's Risk Category: High**

The following device information is taken from the online CDRH Product Code Classification Database:

Device: SET, BIOPSY NEEDLE AND NEEDLE, GASTRO-UROLOGY (FCG), and FORCEPS, BIOPSY, NON-ELECTRIC (COLD BIOPSY FORCEPS) (FCL)

Medical Specialty: Gastroenterology

Product code: FCG and FCL

Device Class: *Class II and Class I for the biopsy forceps cover and the non-electric biopsy forceps*

510(K) Exempt: No, only biopsy forceps cover and the non-electric biopsy forceps are 510(k) exempt

Regulation Number: 876.1075

Identification: A gastroenterology-urology biopsy instrument is a device used to remove, by cutting or aspiration, a specimen of tissue for microscopic examination. This generic type of device includes the biopsy punch, gastrointestinal mechanical biopsy instrument, suction biopsy instrument, gastro-urology biopsy needle and needle set, and nonelectric biopsy forceps. This section does not apply to biopsy instruments that have specialized uses in other medical specialty areas and that are covered by classification regulations in other parts of the device classification regulations.

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the biopsy needle and needle set or non-electric biopsy forceps may engage the vascular system.
- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of biopsy needle and needle set or non-electric biopsy forceps presents an increased risk of infection*.
- 3.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: Yes.**
- 4.) **Question:** *Does a reusable device exist that has an equivalent design and the same intended use as the SUD?* **AMDR Answer: Yes** – Reusable counterparts exist:

Biopsy Needle Sets:

Manufacturer	Model – Cat #	Description	Size
Olympus	NA-1C/54840	Std. Type Biopsy Needle	2.0mm
Olympus	NA-2C/54841	Side Port Type Biopsy Needle	2.0mm
Codman	45-1022	CONE Biopsy Needle	13 G.
Codman	45-1024	CONE Biopsy Needle	15 G.

Biopsy Forceps:

Manufacturer	Model – Cat. #	Description	Size
Olympus	FB-19C-51150	Standard Fenestrated	2.0mm
Olympus	FB-35C-51104	Standard Fenestrated	2.8mm
Olympus	FB-19K-51155	Standard Fenestrated	2.0mm
Olympus	FB-25K-51156	Standard Fenestrated	2.8mm
Olympus	FB-19N-51153	Standard Fenestrated	2.0mm
Olympus	FB-26N-51154	Standard Fenestrated	2.8mm
Olympus	FB-28U-51160	Standard Fenestrated	2.8mm
Olympus	FB-28Y-51147	Standard Fenestrated	2.8mm
Olympus	FB-19CR-51260	Standard Fenestrated	2.0mm Rotate

Manufacturer	Model - Cat. #	Description	Size
Olympus	FB-19KR-51261	Standard Fenestrated	2.0mm Rotate
Olympus	FB-25KR-51261	Standard Fenestrated	2.8mm Rotate
Olympus	FB-22C-51253	Fenestrated Ellipsoid w/needle	2.8mm
Olympus	FB-24K-51251	Fenestrated Ellipsoid w/needle	2.8mm
Olympus	FB-24Q-51256	Fenestrated Ellipsoid w/needle	2.8mm
Olympus	FB-24U-51252	Fenestrated Ellipsoid w/needle	2.8mm
Olympus	FB-24E-51255	Fenestrated Ellipsoid w/needle	2.8mm
Olympus	FB-24KR-51258	Fenestrated Ellipsoid w/needle	2.8mm Rotate
Olympus	FB-22CR-51262	Fenestrated Ellipsoid w/needle	2.8mm Rotate
Olympus	FB-34C-51149	Fenestrated w/needle	2.0mm
Olympus	FB-34K-51148	Fenestrated w/needle	2.0mm
Olympus	FB-23K-51254	Fenestrated w/needle	2.8mm
Olympus	FB-50K-51219	Fenestrated w/needle large cup	3.7mm
Olympus	FB-50Q-51220	Fenestrated w/needle large cup	3.7mm
Olympus	FB-50U-51221	Fenestrated w/needle large cup	3.7mm
Olympus	FB-11K-51305	Alligator Type	2.8mm
Olympus	FB-7U-51303	Alligator Type	2.8mm
Olympus	FB-21C-51157	Fenestrated Ellipsoid	2.0mm
Olympus	FB-20C-51151	Fenestrated Ellipsoid	2.8mm
Olympus	FB-21K-51152	Fenestrated Ellipsoid	2.0mm
Olympus	FB-15C-51631	Alligator Jaws	2.0mm
Olympus	FB-15K-51632	Alligator Jaws	2.0mm
Olympus	FB-36C-51105	Fenestrated w/side teeth	2.8mm
Olympus	FB-36K-51257	Fenestrated w/side teeth	2.8mm
Olympus	FB-38W-51110	Rat Tooth	1.7mm
Olympus	FB-37K-51119	Rat Tooth	2.8mm
Olympus	FB-33N-51164	Std. Fenestrate for Ultrasound	2.0mm
Olympus	FB-44D-51125	Standard Elipsoid	1.2mm
Olympus	FB-45Q-51122	Oval Jaw Static Cup	2.0mm
Olympus	FB-39Q-51120	Oval Fenestrated Rat Tooth	2.0mm
Olympus	FB-40Q-51121	Oval Fenestrated Rat Tooth	2.8mm
Olympus	FB-46Q-51123	Oval Rat Tooth Static Cup	2.0mm
Microvasive	1257	Gastroscope, Piranha	2.2mm
Microvasive	1246	Gastroscope, Piranha w/needle	2.2mm
Microvasive	1210	Gastroscope, Fenestrated	1.8mm
Microvasive	1207	Gastroscope, Fenestrated	2.2mm
Microvasive	1211	Gastroscope, Fenestrated w/needle	1.8mm
Microvasive	1242	Gastroscope, Fenestrated w/needle	2.2mm
Microvasive	1258	Colonoscope, Piranha	2.2mm
Microvasive	1247	Colonoscope, Piranha w/needle	2.2mm
Microvasive	1208	Colonoscope, Fenestrated	2.2mm
Microvasive	1244	Colonoscope, Fenestrated w/needle	2.2mm
Microvasive	1222	Sigmoidoscope, Piranha	1.8mm
Microvasive	1204	Sigmoidoscope, Fenestrated	1.8mm
Microvasive	1206	Sigmoidoscope, Fenestrated	2.2mm
Microvasive	1209	Sigmoidoscope, Fenestrated w/needle	1.8mm
Microvasive	1240	Sigmoidoscope, Fenestrated w/needle	2.2mm
Microvasive	1245	Sigmoidoscope, Piranha w/needle	2.2mm
Microvasive	1256	Sigmoidoscope, Piranha	2.2mm
Microvasive	1223	Sigmoidoscope, Piranha w/needle	1.8mm
Microvasive	1210	Peds Gastroscope, Fenestrated	1.8mm

Manufacturer	Model – Cat. #	Description	Size
Microvasive	1211	Peds Gastroscope, Fenestrated w/needle	1.8mm
Microvasive	1235	3.3mm Jumbo Cup	3.3mm
Microvasive	1236	3.3mm Jumbo Cup w/needle	3.3mm
Wilson-Cook	GBF-1.8-160	Gastroscope Non-Spiked	1.8mm
Wilson-Cook	GBF-1.8-160-S	Gastroscope Spiked	1.8mm
Wilson-Cook	GBF-2.5-160	Gastroscope Non-Spiked	2.5mm
Wilson-Cook	GBF-2.5-160-S	Gastroscope Spiked	2.5mm
Wilson-Cook	AF-1.8-160	Gastroscope Alligator	1.8mm
Wilson-Cook	AF-2.5-160	Gastroscope Alligator	2.5mm
Wilson-Cook	RTF-1.8-160	Gastroscope Rat Tooth	1.8mm
Wilson-Cook	RTF-2.5-160	Gastroscope Rat Tooth	2.5mm
Wilson-Cook	CBF-2.5-230	Colonoscope Non-Spiked	2.5mm
Wilson-Cook	CBF-2.5-230-S	Colonoscope Spiked	2.5mm
Wilson-Cook	AF-2.5-230	Colonoscope Alligator	2.5mm
Wilson-Cook	RTF-2.5-230	Colonoscope Rat Tooth	2.5mm

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) **Question:** Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed? **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of biopsy needle and needle set or non-electric biopsy forceps presents an increased risk of injury*.
 - 2.) **Question:** Could failure of the device cause death, serious injury or permanent impairment? **AMDR Answer: Yes** – The failure of biopsy needles and needle sets or non-electric biopsy forceps - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
 - 3.) **Question:** Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected? **AMDR Answer: No** – While the materials, coatings or components of biopsy needles and needle sets or non-electric biopsy forceps are sometimes altered during their first use, AMDR members do not reprocess damaged biopsy needles and needle sets or non-electric biopsy forceps. Indeed, biopsy needles and needle sets or non-electric biopsy forceps whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be suitable candidates for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess biopsy needles and needle set and non-electric biopsy forceps with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any biopsy needle and needle set or non-electric biopsy forceps are reprocessed. All biopsy needles and needle sets or non-electric biopsy forceps reprocessed by AMDR companies are tested for functionality and are examined under high magnification for any signs of wear or damage. If a problem is detected, the biopsy needle and needle set or non-electric biopsy forceps are rejected and are not returned to the hospital that had requested reprocessing.
- 2a.) **Question:** Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use? **AMDR Answer: No.**

- 2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer: Yes** – AMDR companies visually inspect every biopsy needle and needle set or non-electric biopsy forceps. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the biopsy needle and needle set or non-electric biopsy forceps, it is rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* **No** – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* **Low Risk**
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* **Low Risk**
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* **No** – Low Risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* **Yes** – Low Risk

AMDR's Risk Categorization: LOW RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of biopsy needles and needle sets or non-electric biopsy forceps be made public.

**FDA's Appendix B, Attachment 2 Device Information: laparoscopic dissectors (low), graspers (high) and scissors (high)
FDA's Risk Category: High and Low**

The following device information is taken from the online CDRH Product Code Classification Database:

Device: LAPAROSCOPE, GYNECOLOGIC (AND ACCESSORIES)

Medical Specialty: Obstetrics/Gynecology

Product code: HET

Device Class: II; *Class I for gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources. Such gynecologic laparoscope accessory instruments include: the lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe.*

510(K) Exempt: No - *Only gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources are 510(k) exempt. Such gynecologic laparoscope accessory instruments include: the lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe.*

Regulation Number: 884.1720

Identification: A gynecologic laparoscope is a device used to permit direct viewing of the organs within the peritoneum by a telescopic system introduced through the abdominal wall. It is used to perform diagnostic and surgical procedures on the female genital organs. This generic type of device may include: Trocar and cannula, instruments used through an operating channel, scope preheater, light source and cables, and component parts.

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer:** No – Under the “Spaulding” definition of device criticality, the gynecologic laparoscope (and accessories) may engage the vascular system.
- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer:** No – AMDR companies know of no postmarket information that suggests that proper reprocessing of gynecologic laparoscopes (and accessories) presents an increased risk of infection*.
- 3.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer:** Yes.
- 4.) **Question:** *Does a reusable device exist that has an equivalent design and the same intended use as the SUD?* **AMDR Answer:** Yes – Reusable counterparts exist:

Manufacturer	Model – Cat #	Description	Size
Olympus	A5636	Grasping Forceps	5mm
Olympus	A5638	Coag. Dissecting Forceps	5mm
Olympus	A5467	Micro Scissors	5mm
Olympus	A5650	Curved Micro Scissors	5mm
Olympus	A5264	Hook Scissors, Unipolar	5mm
Olympus	A5609	Spatula Electrode w/channel	5mm
Olympus	A5632	Long Hook Electrode w/channel	5mm
Olympus	A5651	Cholangiocath Clamp	5mm
Olympus	A5630	Angled Dissecting Forceps Unipolar	10mm

Manufacturer	Model – Cat #	Description	Size
Olympus	A5465	Claw Forceps	5mm
Olympus	L0214	Irrigation/Aspiration/Laser Delivery Probe	
Olympus	A5456	Claw Forceps	11mm
Olympus	A5602	Needle Electrode w/channel	5mm
Olympus	A5490	Endoloop Knot Guide	
Olympus	A5494	Endoloop Applicator for Ligature	
Olympus	A5493	Retracting Forceps	5mm
Olympus	A0335	Electrode Cable with Bovie Type Connector	
Olympus	A5486	Trocar/Tocar tube w/triangle tip	11mm
Olympus	A5254	OES II Telescope Trocar	10mm
Olympus	A5257	OES II Telescope Trocar	5mm
Olympus	A5220 for A5201/A5204	Trocar w/triangular tip	5mm
Olympus	A5221 for A5201/A5204	Trocar w/conical tip	5mm
Olympus	A5222 for A5202	Trocar w/triangular tip	4mm
Olympus	A5223 for A5202	Trocar w/conical tip	4mm
Olympus	A5224 for A5203/A5205	Trocar w/triangular tip	10mm
Olympus	A5225 for A5203/A5205	Trocar w/conical tip	10mm
Olympus	A5228 for A5218/A5219	Trocar w/triangular tip	10mm short
Olympus	A5229 for A5218/A5219	Trocar w/conical tip	10mm short
Olympus	A5261	Rigid Biopsy Forceps w/spoon jaws	5mm short
Olympus	A5241	Rigid Biopsy Forceps w/spoon jaws	5mm short
Olympus	A5262	Rigid Biopsy Forceps w/cutting jaws	5mm short
Olympus	A5242	Rigid Biopsy Forceps w/cutting jaws	5mm short
Olympus	A5263	Rigid Grasping Forceps	5mm short
Olympus	A5243	Rigid Grasping Forceps	5mm short
Olympus	A5264	Hook Scissors	5mm short
Olympus	A5244	Hook Scissors	5mm short
Olympus	A5265	Hook Forceps	5mm short
Olympus	A5245	Hook Forceps	5mm short
Olympus	A5361	Rigid Biopsy Forceps w/spoon jaws	4mm short
Olympus	A5341	Rigid Biopsy Forceps w/spoon jaws	4mm short
Olympus	A5362	Rigid Biopsy Forceps w/cutting jaws	4mm short
Olympus	A5342	Rigid Biopsy Forceps w/cutting jaws	4mm short
Olympus	A5363	Rigid Grasping Forceps	4mm short
Olympus	A5343	Rigid Grasping Forceps	4mm short
Olympus	A5364	Hook Scissors	4mm short
Olympus	A5344	Hook Scissors	4mm short
Olympus	A5365	Hook Forceps	4mm short
Olympus	A5345	Hook Forceps	4mm short

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) *Question: Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed? AMDR*

Answer: No – AMDR companies know of no postmarket information that suggests that proper reprocessing of gynecologic laparoscopes (and accessories) presents an increased risk of injury*.

- 2.) **Question: Could failure of the device cause death, serious injury or permanent impairment?** **AMDR Answer: Yes** – The failure of gynecologic laparoscope (and accessories) - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) **Question: Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?** **AMDR Answer: No** – While the materials, coatings or components of a gynecologic laparoscope (and accessories) are sometimes altered during their first use, AMDR members do not reprocess damaged gynecologic laparoscopes. Indeed, a gynecologic laparoscope whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess a gynecologic laparoscope (and accessories) with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any gynecologic laparoscope (and accessories) is reprocessed. Every gynecologic laparoscope reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the gynecologic laparoscope is rejected and is not returned to the hospital that had requested reprocessing.
- 2a.) **Question: Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?** **AMDR Answer: No.**
- 2b.) **Question: Can visual inspection determine if performance has been affected?** **AMDR Answer: Yes** – AMDR companies visually inspect every gynecologic laparoscope. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the gynecologic laparoscope, it is rejected and is not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* **No** – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* **Low Risk**
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* **Low Risk**
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* **No** – Low Risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* **Yes** – Low Risk

AMDR's Risk Categorization: LOW RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of gynecologic laparoscope (and accessories) be made public.

FDA's Appendix B, Attachment 2 Device Information: biopsy forceps
FDA's Risk Category: High

The following device information is taken from the online CDRH Product Code Classification Database:

Device: FORCEPS, BIOPSY, GYNECOLOGICAL

Medical Specialty: Obstetrics/Gynecology

Product code: HFB

Device Class: 1

510(K) Exempt: Yes - *Only amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps are 510(k) exempt.*

Regulation Number: 884.4530

Identification: An obstetric-gynecologic specialized manual instrument is one of a group of devices used during obstetric-gynecologic procedures to perform manipulative diagnostic and surgical functions (e.g., dilating, grasping, measuring, and scraping), where structural integrity is the chief criterion of device performance.

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the gynecological biopsy forceps may engage the vascular system.
- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of gynecological biopsy forceps presents an increased risk of infection*.
- 3.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: Yes.**
- 4.) **Question:** *Does a reusable device exist that has an equivalent design and the same intended use as the SUD?* **AMDR Answer: Yes** – Reusable counterparts exist:

Manufacturer	Model – Cat #	Description	Size
Fine Instruments	924-991	Tischler Biopsy Punch Forceps	3 x 7mm bite
Fine Instruments	924-996	Eppendorfer Biopsy Punch Forceps	4.5 x 6.5mm bite
Fine Instruments	924-989	Kevorkian-Younger Biopsy Punch Forceps	3.5 x 8mm bite

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of gynecological biopsy forceps presents an increased risk of injury*.
- 2.) **Question:** *Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer: Yes** – The failure of gynecological biopsy forceps - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) **Question:** *Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer: No** – While the materials, coatings or components of gynecological biopsy forceps are sometimes altered during their first use, AMDR members do not reprocess damaged gynecological biopsy forceps. Indeed, gynecological biopsy forceps whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be suitable candidates for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies

have validated cleaning and sterilization protocols that enable them to reprocess gynecological biopsy forceps with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before gynecological biopsy forceps are reprocessed. All gynecological biopsy forceps reprocessed by AMDR companies are tested for functionality and are examined under high magnification for any signs of wear or damage. If a problem is detected, the gynecological biopsy forceps are rejected and are not returned to the hospital that had requested reprocessing.

2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer: No.**

2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer: Yes** – AMDR companies visually inspect all gynecological biopsy forceps. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the gynecological biopsy forceps, they are rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* **No** – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* **Low Risk**
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* **Low Risk**
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* **No** – Low Risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* **Yes** – Low Risk

AMDR's Risk Categorization: LOW RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of gynecological biopsy forceps be made public.

FDA's Appendix B, Attachment 2 Device Information: Keratome Blade
FDA's Risk Category: High

The following device information is taken from the online CDRH Product Code Classification Database:

Devices: KERATOME, BATTERY-POWERED, KERATOME, A-C POWERED, and KERATOME, WATER JET

Medical Specialty: Ophthalmic
Product code: HMY, HNO, MYD
Device Class: 1
510(K) Exempt: No
Regulation Number: 886.4370

Identification: A keratome is an AC-powered or battery-powered device intended to shave tissue from sections of the cornea for a lamellar (partial thickness) transplant.

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the A-C powered, battery-powered or water jet keratome may engage the vascular system.
- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of A-C powered, battery-powered or water jet keratomes presents an increased risk of infection*.
- 3.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: Yes.**
- 4.) **Question:** *Does a reusable device exist that has an equivalent design and the same intended use as the SUD?* **AMDR Answer: Yes** – Reusable counterparts exist:

Manufacturer	Model – Cat #	Description	Size
V. Mueller	OP830	CASTROVIEJO Keratome	4 x 13mm Angled
V. Mueller	OP750	JAEGER Keratome	Lg Blade 45°
V. Mueller	OP751	JAEGER Keratome	Med Blade 45°
V. Mueller	OP752	JAEGER Keratome	Sm Blade 45°

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of A-C powered, battery-powered or water jet keratomes presents an increased risk of injury*.
- 2.) **Question:** *Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer: Yes** – The failure of an A-C powered, battery-powered or water jet keratome - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) **Question:** *Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or reesterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer: No** – While the materials, coatings or components of A-C powered, battery-powered or water jet keratomes are sometimes altered during their first use, AMDR members do not reprocess damaged A-C powered, battery-powered or water jet keratomes. Indeed, an A-C

powered, battery-powered or water jet keratome whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess A-C powered, battery-powered or water jet keratomes with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any A-C powered, battery-powered or water jet keratome is reprocessed. Every A-C powered, battery-powered or water jet keratome reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the A-C powered, battery-powered or water jet keratome is rejected and is not returned to the hospital that had requested reprocessing.

- 2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer:** No.
- 2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer:** Yes – AMDR companies visually inspect every A-C powered, battery-powered or water jet keratome. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the A-C powered, battery-powered or water jet keratome, it is rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* No – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* Low Risk
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* Low Risk
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* No – Low risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* Yes – Low Risk

AMDR's Risk Categorization: LOW RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of A-C powered, battery-powered or water jet keratomes be made public.

FDA's Appendix B, Attachment 2 Device Information: Biopsy Forceps
FDA's Risk Category: High

The following device information is taken from the online CDRH Product Code Classification Database:

Device: FORCEPS, BIOPSY, ELECTRIC

Medical Specialty: Gastroenterology

Product code: KGE

Device Class: 2

510(K) Exempt: No

Regulation Number: 876.4300

Identification: An endoscopic electrosurgical unit and accessories is a device used to perform electrosurgical procedures through an endoscope. This generic type of device includes the electrosurgical generator, patient plate, electric biopsy forceps, electrode, flexible snare, electrosurgical alarm system, electrosurgical power supply unit, electrical clamp, self-opening rigid snare, flexible suction coagulator electrode, patient return wristlet, contact jelly, adaptor to the cord for transurethral surgical instruments, the electric cord for transurethral surgical instruments, and the transurethral desiccator.

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the electric biopsy forceps may engage the vascular system.
- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of electric biopsy forceps presents an increased risk of infection*.
- 3.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: Yes.**
- 4.) **Question:** *Does a reusable device exist that has an equivalent design and the same intended use as the SUD?* **AMDR Answer: Yes** – Reusable counterparts exist:

Manufacturer	Model – Cat. #	Description	Size
Olympus	FD-1L-54421S	Hot Biopsy Forceps	2.8mm
Olympus	FD-2L-54423S	Hot Biopsy Forceps	3.7mm
Olympus	FD-1U-54422S	Hot Biopsy Forceps	2.8mm
Olympus	FD-2U-54424S	Hot Biopsy Forceps	3.7mm
Olympus	SD-15U-54279	Oval Snare	
Microvasive	1230	Hot Biopsy Forceps	2.2mm
Microvasive	1231	Hot Biopsy Forceps	2.2mm

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – AMDR companies know of no postmarket information that suggests that proper reprocessing of electric biopsy forceps presents an increased risk of injury*.
- 2.) **Question:** *Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer: Yes** – The failure of electric biopsy forceps - new or reprocessed - could potentially cause death, serious injury or permanent impairment.

- 3.) **Question:** *Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or reesterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer:** No – While the materials, coatings or components of electric biopsy forceps are sometimes altered during their first use, AMDR members do not reprocess damaged electric biopsy forceps. Indeed, electric biopsy forceps whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be suitable candidates for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess electric biopsy forceps with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any electric biopsy forceps are reprocessed. All electric biopsy forceps reprocessed by AMDR companies are tested for functionality and are examined under high magnification for any signs of wear or damage. If a problem is detected, the electric biopsy forceps are rejected and are not returned to the hospital that had requested reprocessing.
- 2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer:** No.
- 2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer:** Yes – AMDR companies visually inspect all electric biopsy forceps. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of electric biopsy forceps, they are rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* No – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* Low Risk
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* Low Risk
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* No – Low risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* Yes – Low Risk

AMDR's Risk Categorization: LOW RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of electric biopsy forceps be made public.

**FDA's Appendix B, Attachment 2 Device Information: Biliary sphincterotomes
FDA's Risk Category: High**

The following device information is taken from the CDRH Database:

Device: UNIT, ELECTROSURGICAL, ENDOSCOPIC (WITH OR WITHOUT ACCESSORIES)

Medical Specialty: Gastroenterology
Product code: KNS
Device Class: 2
510(K) Exempt: No
Regulation Number: 876.4300

Identification: An endoscopic electrosurgical unit and accessories is a device used to perform electrosurgical procedures through an endoscope. This generic type of device includes the electrosurgical generator, patient plate, electric biopsy forceps, electrode, flexible snare, electrosurgical alarm system, electrosurgical power supply unit, electrical clamp, self-opening rigid snare, flexible suction coagulator electrode, patient return wristlet, contact jelly, adaptor to the cord for transurethral surgical instruments, the electric cord for transurethral surgical instruments, and the transurethral desiccator.

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the electrical endoscopic unit (with or without accessories) may engage the vascular system.

- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – There is substantial postmarket information that supports the safety of proper reprocessing of the percutaneous conduction tissue ablation electrode*. See, for example:
 Kozarek, R.A., Raltz, S.L., Ball, T.J., Patterson, D.J., Brandabur, J.J., “Reuse of Disposable Sphincterotomes for Diagnostic and Therapeutic ERCP: A One-Year Prospective Study,” **Gastrointestinal Endoscopy**, January 1999, Vol. 49, No.1, p.p. 39-42
 Kozarek, R.A., Sumida, S.E., Raltz, S.L., Merriam, L.D., Irizarry, D.C., “In vitro Evaluation of Wire Integrity and Ability to Reprocess Single-Use Sphincterotomes,” **Gastrointestinal Endoscopy**, February 1997, Vol. 45, No. 2, p.p. 117-121

- 3.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: Yes.**

- 4.) **Question:** *Does a reusable device exist that has an equivalent design and the same intended use as the SUD?* **AMDR Answer: Yes** – Reusable counterparts exist:

Manufacturer	Model – Cat. #	Description	Size
Olympus	FD-1L-54421S	Hot Biopsy Forceps	2.8mm
Olympus	FD-2L-54423S	Hot Biopsy Forceps	3.7mm
Olympus	FD-1U-54422S	Hot Biopsy Forceps	2.8mm
Olympus	FD-2U-54424S	Hot Biopsy Forceps	3.7mm
Olympus	SD-15U-54279	Oval Snare	
Microvasive	1230	Hot Biopsy Forceps	2.2mm
Microvasive	1231	Hot Biopsy Forceps	2.2mm

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer:** No – AMDR companies know of no postmarket information that suggests that proper reprocessing of an electrical endoscopic unit (with or without accessories) poses an increased risk of injury*.
- 2.) **Question:** *Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer:** Yes – The failure of an electrical endoscopic unit (with or without accessories) - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) **Question:** *Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer:** No – While the materials, coatings or components of an electrical endoscopic unit (with or without accessories) are sometimes altered during their first use, AMDR members do not reprocess damaged electrical endoscopic units. Indeed, an electrical endoscopic unit (with or without accessories) whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess electrical endoscopic units (with or without accessories) with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any electrical endoscopic unit (with or without accessories) is reprocessed. Every electrical endoscopic unit reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the electrical endoscopic unit is rejected and is not returned to the hospital that had requested reprocessing.
- 2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer:** No.
- 2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer:** Yes – AMDR companies visually inspect every electrical endoscopic unit (with or without accessories). This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the electrical endoscopic unit, it is rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* No – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* Low Risk
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* Low Risk
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* No – Low risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* Yes – Low Risk

AMDR's Risk Categorization: LOW RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of electrical endoscopic unit (with or without accessories) be made public.

FDA's Appendix B, Attachment 2 Device Information: Cardiac Ablation Catheter
FDA's Risk Category: High

The following device information is taken from the online CDRH Product Code Classification Database:

Device: ELECTRODE, PERCUTANEOUS, CONDUCTION TISSUE ABLATION

Common Name: EP Catheter
Medical Specialty: Cardiovascular
Product Code: LPB
Device Class: 3
510(k) Exempt: No (PMA)
Identification: None available

Flowchart 1 – Infection Risk:

- 1.) **Question:** *Is the SUD a non-critical device?* **AMDR Answer: No** – Under the “Spaulding” definition of device criticality, the percutaneous conduction tissue ablation electrode engages the vascular system, meaning it enters the bloodstream.
- 2.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of infection when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – There is substantial postmarket information that supports the safety of proper reprocessing of the percutaneous conduction tissue ablation electrode*. See, for example:
Aton, EA, Murray, P, Frase, V, Conaway, L, Cain, ME, “*Safety of Reusing Cardiac Electrophysiology Catheters: A Prospective Study.*” **American Journal of Cardiology**, 1994, 74: 1173-1175
Avitall, B, Kahn, M, Drum, D, Jazayeri, M, Hare, J, “*Repeated Use of Ablation Catheters: A Prospective Study.*” **Journal of the American College of Cardiology**, 1993, 22: 1367-1372
Dunnigan, A, Roberts, C, McNamara, M, Benson, DW, Benditt, DG, “*Success of Re-Use of Cardiac Electrode Catheters.*” **American Journal of Cardiology**, 1987, 60: 807-810
Ferrell, M, Wolf, CE, Ellenbogen, KA, Wood, MA, Clemo, HF, Gilligan, DM, “*Ethylene oxide on electrophysiology catheters following resterilization: implications for catheter reuse.*” **American Journal of Cardiology**, 1997, 80: 1558-1561
O'Donoghue, S, Platia, EV, “*Reuse of Pacing Catheters: A Survey of Safety and Efficacy.*” **Pacing and Clinical Electrophysiology**, 1988, 11: 1279-1280
- 3.) **Question:** *Does the SUD include features that could impede thorough cleaning and adequate sterilization/disinfection?* **AMDR Answer: No** – A percutaneous conduction tissue ablation electrode is a sealed lumen device that is reprocessed regularly by AMDR companies without any cleaning difficulties.

AMDR Conclusion: Low Risk

Flowchart 2 – Inadequate Performance Risk:

- 1.) **Question:** *Does postmarket information suggest that using the reprocessed SUD may present an increased risk of injury when compared to the use of an SUD that has not been reprocessed?* **AMDR Answer: No** – Postmarket information suggests that proper reprocessing of a percutaneous conduction tissue ablation electrode poses no increased risk of injury (see articles listed in Flowchart 1)*.
- 2.) **Question:** *Could failure of the device cause death, serious injury or permanent impairment?* **AMDR Answer: Yes** – The failure of a percutaneous conduction tissue ablation electrode - new or reprocessed - could potentially cause death, serious injury or permanent impairment.
- 3.) **Question:** *Does the SUD contain any materials, coatings or components that may be damaged or altered by a single use or by reprocessing and/or resterilization in such a way that the performance of the device may be adversely affected?* **AMDR Answer: No** – While the materials, coatings or components of percutaneous conduction tissue ablation electrodes are sometimes altered during their first use, AMDR members do not reprocess damaged percutaneous conduction tissue ablation electrodes. Indeed, a

percutaneous conduction tissue ablation electrode whose materials, coatings or components have been damaged or altered by a single use in such a way that the performance of the device has been adversely affected would not be a suitable candidate for reprocessing and would be rejected by AMDR companies. With respect to the potential effects of reprocessing, AMDR companies have validated cleaning and sterilization protocols that enable them to reprocess percutaneous conduction tissue ablation electrodes with no damage to the materials, coatings or components. This is achieved through AMDR companies' research, reverse engineering, and the cleaning and sterilization protocol validation process that is completed before any percutaneous conduction tissue ablation electrode is reprocessed. Every percutaneous conduction tissue ablation electrode reprocessed by AMDR companies is tested for functionality and is examined under high magnification for any signs of wear or damage. If a problem is detected, the percutaneous conduction tissue ablation electrode is rejected and is not returned to the hospital that had requested reprocessing.

- 2a.) **Question:** *Are there recognized consensus performance standards, performance tests recommended by the OEM or a CDRH guidance document that may be used to determine if the performance of the SUD has been altered due to reprocessing and use?* **AMDR Answer:** No.
- 2b.) **Question:** *Can visual inspection determine if performance has been affected?* **AMDR Answer:** Yes – AMDR companies visually inspect every percutaneous conduction tissue ablation electrode. This visual inspection encompasses both functionality testing and examination under high magnification for any signs of wear or damage. If reprocessing has affected the performance of the percutaneous conduction tissue ablation electrode, it is rejected and not returned to the hospital that had requested reprocessing.

AMDR Conclusion: Low Risk

Work Sheet:

- 1.) *Is the SUD an implant as defined in 21 CFR Part 860.3(d)?* No – Not an implant
- 2.) *What is the risk of infection according to Flowchart 1?* Low Risk
- 3.) *What is the risk of inadequate performance according to Flowchart 2?* Low Risk
- 4.) *Did the SUD result in a Moderate Risk on Flowchart 1 or 2? If so, the SUD is categorized as Moderate Risk.* No – Low risk
- 5.) *Did the SUD result in a Low Risk on Flowcharts 1 AND 2?* Yes – Low Risk

AMDR's Risk Categorization: LOW RISK

* AMDR respectfully requests that all postmarket information utilized by FDA in its risk assessment of percutaneous conduction tissue ablation electrodes be made public.

ATTACHMENT N

	A	B	C	D	E	F
1	Devices Labeled for Single-Use that, to the Best of AMDR's Knowledge, Are Currently Being Reprocessed					
2	Medical Specialty	Device Name	Class	510k Exempt (yes/no)	Regulation Number	ProCode
3	AN	CIRCUIT, BREATHING (W CONNECTOR, ADAPTOR, Y PIECE)	1	Y	868.5240	CAI
4	AN	CATHETER, NASAL, OXYGEN	1	Y	868.5350	BZB
5	AN	MASK, GAS, ANESTHETIC	1	Y	868.5550	BSJ
6	AN	MOUTHPIECE, BREATHING	1	Y	868.5620	BYP
7	AN	CATHETERS, SUCTION, TRACHEOBRONCHIAL	1	Y	868.6810	BSY
8	CV	CUFF, BLOOD-PRESSURE	2	N	870.1120	DXQ
9	CV	CATHETER, INTRAVASCULAR, DIAGNOSTIC	2	N	870.1200	DQO
10	CV	CATHETER, ELECTRODE RECORDING, OR PROBE, ELECTRODE RECORDING	2	N	870.1220	DRF
11	CV	CATHETER, INTRACARDIAC MAPPING, HIGH-DENSITY ARRAY	2	N	870.1220	MTD
12	CV	CATHETER, OXIMETER, FIBEROPTIC	2	N	870.1230	DQE
13	CV	CATHETER, STEERABLE	2	N	870.1280	DRA
14	CV	SYSTEM, CATHETER CONTROL, STEERABLE	2	N	870.1290	DXX
15	CV	WIRE, GUIDE, CATHETER	2	N	870.1330	DQX
16	CV	TROCAR	2	N	870.1390	DRC
17	CV	ACTUATOR, SYRINGE, INJECTOR TYPE	2	N	870.1670	DQF
18	CV	OXIMETER	2	N	870.2700	DQA
19	CV	OXIMETER, TISSUE SATURATION	2	N	870.2700	MUD
20	CV	SYSTEM, BALLOON, INTRA-AORTIC AND CONTROL	3	N	870.3535	DSP
21	CV	CLAMP, VASCULAR	2	N	870.4450	DXC
22	CV	DEVICE, STABILIZER, HEART	1	N	870.4500	MWS
23	CV	STRIPPER, VEIN, EXTERNAL	2	N	870.4885	DWQ
24	CV	SLEEVE, LIMB, COMPRESSIBLE	2	N	870.5800	JOW
25	DE	BUR, DENTAL	1	Y	872.3240	EJL
26	DE	SAW, BONE, AC-POWERED	2	N	872.4120	DZH
27	DE	DRILL, BONE, POWERED	2	N	872.4120	DZI
28	DE	DRIVER, WIRE, AND BONE DRILL, MANUAL	2	N	872.4120	DZJ
29	DE	DRILL, DENTAL, INTRAORAL	1	Y	872.4130	DZA
30	DE	BRACKET, METAL, ORTHODONTIC	1	Y	872.5410	EJF
31	DE	BRACKET, PLASTIC, ORTHODONTIC	2	N	872.5470	DYW
32	EN	BUR	1	Y	874.4140	EQJ
33	EN	SCISSORS, EAR	1	Y	874.4420	JZB
34	EN	TROCAR, LARYNGEAL	1	Y	874.4420	KAB

	A	B	C	D	E	F
35	EN	KNIFE, NASAL				
36	EN	SCISSORS, NASAL	1	Y	874.4420	KAS
37	EN	TROCAR, SINUS	1	Y	874.4420	KBD
38	EN	KNIFE, TONSIL	1	Y	874.4420	KBG
39	EN	TROCAR, TRACHEAL	1	Y	874.4420	KBQ
40	EN	LASER, MICROSURGICAL ARGON, FOR USES OTHER THAN OTOTOLOGY, INCLUDING LARYNGOLOGY & GENERAL U	1	Y	874.4420	KCI
41	EN	LASER, MICROSURGICAL ARGON, FOR USE IN OTOTOLOGY	2	N	874.4490	LMS
42	EN	LASER, ENT MICROSURGICAL CARBON-DIOXIDE	2	N	874.4490	LXR
43	EN	FORCEPS, BIOPSY, BRONCHOSCOPE (NON-RIGID)	2	N	874.4500	EWG
44	EN	FORCEPS, BIOPSY, BRONCHOSCOPE (RIGID)	2	N	874.4680	BWH
45	GU	INSTRUMENT, BIOPSY, MECHANICAL, GASTROINTESTINAL	2	N	874.4680	JEK
46	GU	SET, BIOPSY NEEDLE AND NEEDLE, GASTRO-UROLOGY	2	N	876.1075	FCF
47	GU	PUNCH, BIOPSY	2	N	876.1075	FCG
48	GU	FORCEPS, BIOPSY, NON-ELECTRIC	2	N	876.1075	FCI
49	GU	COVER, BIOPSY FORCEPS	**1	Y	876.1075	FCL
50	GU	INSTRUMENT, BIOPSY	1	Y	876.1075	FFF
51	GU	BRUSH, CYTOLOGY, FOR ENDOSCOPE	2	N	876.1075	KNW
52	GU	NEEDLE, PNEUMOPERITONEUM, SPRING LOADED	2	N	876.1500	FDX
53	GU	NEEDLE, PNEUMOPERITONEUM, SIMPLE	2	N	876.1500	FHO
54	SU	LAPAROSCOPE, GENERAL & PLASTIC SURGERY	2	N	876.1500	FHP
55	GU	ENDOSCOPE, AC-POWERED AND ACCESSORIES	2	N	876.1500	G CJ
56	GU	ENDOSCOPE, DIRECT VISION	2	N	876.1500	GCP
57	GU	ENDOSCOPE AND/OR ACCESSORIES	2	N	876.1500	GCR
58	OP	ENDOILLUMINATOR	2	N	876.1500	KOG
59	GU	UNIT, ELECTROSURGICAL	2	N	876.1500	MPA
60	GU	ELECTRODE, ELECTROSURGICAL, ACTIVE, UROLOGICAL	2	N	876.4300	FAR
61	GU	SNARE, FLEXIBLE	2	N	876.4300	FAS
62	GU	ELECTRODE, FLEXIBLE SUCTION COAGULATOR	2	N	876.4300	FDI
63	GU	FORCEPS, BIOPSY, ELECTRIC	2	N	876.4300	FEH
64	GU	UNIT, ELECTROSURGICAL, ENDOSCOPIC (WITH OR WITHOUT ACCESSORIES)	2	N	876.4300	KGE
65	GU	LIGATOR, HEMORRHOIDAL	2	N	876.4300	KNS
66	GU	DISLODGER, STONE, BASKET, URETERAL, METAL	2	N	876.4400	FHN
67	GU	DISLODGER, STONE, FLEXIBLE	2	Y	876.4680	FFL
68	GU	SNARE, NON-ELECTRICAL	2	Y	876.4680	FGO
69	GU	HOLDER, NEEDLE	1	Y	876.4730	FGX
70	GU	CANNULA AND TROCAR, SUPRAPUBIC, NON-DISPOSABLE	1	Y	876.4730	FHQ
			2	N	876.5090	FBM

	A	B	C	D	E	F
71	GU	TROCAR, GASTRO-UROLOGY				
72	GU	CATHETER, UROLOGICAL	2	N	876.5090	FBQ
73	GU	ACCESSORIES, BLOOD CIRCUIT, HEMODIALYSIS	2	N	876.5130	KOD
74	SU	SPLINT, EXTREMITY, INFLATABLE, EXTERNAL	2	N	876.5820	KOC
75	SU	SPLINT, EXTREMITY, NONINFLATABLE, EXTERNAL	1	Y	878.3900	FZF
76	SU	UNIT, ELECTROSURGICAL AND COAGULATION, WITH ACCESSORIES	1	Y	878.3910	FYH
77	SU	ELECTROSURGICAL DEVICE	2	N	878.4400	BWA
78	SU	DEVICE, ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES	2	N	878.4400	DWG
79	SU	APPARATUS, ELECTROSURGICAL	2	N	878.4400	GEI
80	SU	ELECTRODE, ELECTROSURGICAL	2	N	878.4400	HAM
81	SU	NEEDLE, BIOPSY, CARDIOVASCULAR	2	N	878.4400	JOS
82	SU	KNIFE, SURGICAL	1	Y	878.4800	DWO
83	SU	APPARATUS, SUTURING, STOMACH AND INTESTINAL	1	Y	878.4800	EMF
84	SU	LANCET, BLOOD	1	Y	878.4800	FHM
85	SU	CHISEL, SURGICAL, MANUAL	1	Y	878.4800	FMK
86	SU	CURETTE, SURGICAL	1	Y	878.4800	FZO
87	SU	CUTTER, SURGICAL	1	Y	878.4800	FZS
88	SU	RASP, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	FZT
89	SU	RETRACTOR, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GAC
90	SU	SNARE, SURGICAL	1	Y	878.4800	GAD
91	SU	SPATULA, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GAE
92	SU	STAPLER, SURGICAL	1	Y	878.4800	GAF
93	SU	STRIPPER, VEIN, DISPOSABLE	1	Y	878.4800	GAG
94	SU	HOOK, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GAJ
95	SU	GOUGE, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GDG
96	SU	DISSECTOR, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GDH
97	SU	CLAMP, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GDI
98	SU	SAW, MANUAL AND ACCESSORIES	1	Y	878.4800	GDJ
99	SU	SCALPEL, ONE-PIECE	1	Y	878.4800	GDR
100	SU	HANDLE, SCALPEL	1	Y	878.4800	GDX
101	SU	BRUSH, BIOPSY, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GDZ
102	SU	APPLIER, STAPLE, SURGICAL,	1	Y	878.4800	GEE
103	SU	FORCEPS, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GEF
104	SU	BLADE, SCALPEL	1	Y	878.4800	GEN
105	SU	RETRACTOR, MANUAL	1	Y	878.4800	GES
106	SU	SAW, MANUAL, AND ACCESSORIES	1	Y	878.4800	GZW
			1	Y	878.4800	HAC

	A	B	C	D	E	F
107	SU	APPLIER, HEMOSTATIC CLIP	1	Y	878.4800	HBT
108	SU	SAW	1	Y	878.4800	HSO
109	SU	FORCEPS	1	Y	878.4800	HTD
110	SU	CURETTE	1	Y	878.4800	HTF
111	SU	RASP	1	Y	878.4800	HTR
112	SU	INSTRUMENT, CUTTING, ORTHOPEDIC	1	Y	878.4800	HTZ
113	SU	OSTEOTOME	1	Y	878.4800	HWM
114	SU	CLAMP	1	Y	878.4800	HXD
115	SU	RETRACTOR	1	Y	878.4800	HXM
116	SU	SPATULA, ORTHOPEDIC	1	Y	878.4800	HXR
117	SU	CHISEL, MASTOID	1	Y	878.4800	JYD
118	SU	INSTRUMENT, SURGICAL, DISPOSABLE	1	Y	878.4800	KDC
119	SU	HOOK, BONE	1	Y	878.4800	KIK
120	SU	SCISSORS, GENERAL USE, SURGICAL	1	Y	878.4800	LRW
121	SU	INSTRUMENT, MANUAL, GENERAL SURGICAL	1	Y	878.4800	MDM
122	SU	INSTRUMENT, MANUAL, SURGICAL, GENERAL USE	1	Y	878.4800	MDW
123	SU	LASER INSTRUMENT, SURGICAL, POWERED	2	N	878.4810	GEX
124	SU	BLADE, SAW, SURGICAL, CARDIOVASCULAR	1	Y	878.4820	DWH
125	SU	SAW, ELECTRICALLY POWERED	1	Y	878.4820	DWI
126	SU	MOTOR, SURGICAL INSTRUMENT, PNEUMATIC POWERED	1	Y	878.4820	GET
127	SU	MOTOR, SURGICAL INSTRUMENT, AC-POWERED	1	Y	878.4820	GEY
128	SU	BLADE, SAW, GENERAL & PLASTIC SURGERY, SURGICAL	1	Y	878.4820	GFA
129	SU	DERMATOME	1	Y	878.4820	GFD
130	SU	BUR, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4820	GFF
131	SU	BIT, SURGICAL	1	Y	878.4820	GFG
132	SU	SAW, POWERED, AND ACCESSORIES	1	Y	878.4820	HAB
133	SU	CHISEL (OSTEOTOME)	1	Y	878.4820	KDG
134	SU	SAW, PNEUMATICALLY POWERED	1	Y	878.4820	KFK
135	SU	TOURNIQUET, NONPNEUMATIC	1	Y	878.5900	GAX
136	SU	TOURNIQUET, PNEUMATIC	1	Y	878.5910	KCY
137	HO	MATTRESS, FLOTATION THERAPY, NON-POWERED	1	Y	880.5150	IKY
138	HO	LIFT, PATIENT, NON-AC-POWERED	1	Y	880.5510	FSA
139	HO	MATTRESS, AIR FLOTATION, ALTERNATING PRESSURE	2	Y	880.5550	FNM
140	HO	MATTRESS, WATER, TEMPERATURE REGULATED	1	Y	880.5560	FOH
141	HO	NEEDLE, HYPODERMIC, SINGLE LUMEN	2	N	880.5570	FMI
142	HO	SYRINGE, PISTON	2	N	880.5860	FMF

	A	B	C	D	E	F
143	HO	COVER, MATTRESS (MEDICAL PURPOSES)				
144	HO	SCISSORS, MEDICAL, DISPOSABLE	1	Y	880.6190	FMW
145	HO	SYRINGE, IRRIGATING	1	Y	880.6820	JOK
146	NE	INSTRUMENT, CLIP FORMING/CUTTING	1	Y	880.6960	KYZ
147	NE	DRILLS, BURRS, TREPHINES & ACCESSORIES (MANUAL)	1	Y	882.4190	HBS
148	NE	DRILLS, BURRS, TREPHINES & ACCESSORIES (COMPOUND, POWERED)	2	N	882.4300	HBG
149	NE	DRILLS, BURRS, TREPHINES & ACCESSORIES (SIMPLE, POWERED)	2	N	882.4305	HBF
150	OB	LAPAROSCOPE, GYNECOLOGIC (AND ACCESSORIES)	2	N	882.4310	HBE
151	OB	INSUFFLATOR, LAPAROSCOPIC	**2	N	884.1720	HET
152	OB	ELECTROCAUTERY, ENDOSCOPIC AND ACCESSORIES	2	N	884.1730	HIF
153	OB	ELECTROCAUTERY, GYNECOLOGIC (AND ACCESSORIES)	3	N	884.4100	HIM
154	OB	COAGULATOR-CUTTER, ENDOSCOPIC, BIPOLAR (AND ACCESSORIES)	2	N	884.4120	HGI
155	OB	COAGULATOR, LAPAROSCOPIC, UNIPOLAR (AND ACCESSORIES)	3	N	884.4150	HIN
156	OB	COAGULATOR, HYSTEROSCOPIC (AND ACCESSORIES)	2	N	884.4160	HFG
157	OB	COAGULATOR, CULDOSCOPIIC (AND ACCESSORIES)	2	N	884.4160	HFH
158	OB	COAGULATOR-CUTTER, ENDOSCOPIC, UNIPOLAR (AND ACCESSORIES)	2	N	884.4160	HFI
159	OB	SCISSORS, UMBILICAL	2	N	884.4160	KNF
160	OB	SCISSORS, EPISIOTOMY	1	Y	884.4520	HDJ
161	OB	FORCEPS, BIOPSY, GYNECOLOGICAL	1	Y	884.4520	HDK
162	OB	LASER, SURGICAL, GYNECOLOGIC	1	Y	884.4530	HFB
163	OB	LASER, NEODYMIUM:YAG FOR GYNECOLOGIC USE	2	N	884.4550	HHR
164	OP	KNIFE, OPHTHALMIC	2	N	884.4550	LLW
165	OP	KERATOME, BATTERY-POWERED	1	Y	886.4350	HNN
166	OP	KERATOME, AC-POWERED	1	N	886.4370	HMY
167	OP	KERATOME, WATER JET	1	N	886.4370	HNO
168	OP	LASER, OPHTHALMIC	1	N	886.4370	MYD
169	OP	UNIT, PHACOFRAGMENTATION	2	N	886.4390	HQF
170	OP	FLUIDIC, PHACOEMULSIFICATION/PHACOFRAGMENTATION	2	N	886.4670	HQC
171	OP	PHOTOCOAGULATOR AND ACCESSORIES	2	N	886.4670	MUS
172	OR	ARTHROSCOPE **Associated Instruments	2	N	886.4690	HQB
173	OR	COMPONENT, TRACTION, INVASIVE	2 **1	N	888.1100	HRX
174	OR	SCISSORS	2	N	888.3040	JEC
175	OR	REAMER	1	Y	888.4540	HRR
176	OR	KNIFE, ORTHOPEDIC	1	Y	888.4540	HTO
177	OR	BURR	1	Y	888.4540	HTS
178	OR	BIT, DRILL	1	Y	888.4540	HTT
			1	Y	888.4540	HTW

	A	B	C	D	E	F	
179	OR	RONGEUR					
180	OR	TREPHINE	1	Y	888.4540	HTX	
181	OR	COUNTERSINK	1	Y	888.4540	HWK	
182	OR	TAP, BONE	1	Y	888.4540	HWW	
183	OR	STAPLE DRIVER	1	Y	888.4540	HWX	
184	OR	HOLDER, NEEDLE; ORTHOPEDIC	1	Y	888.4540	HXJ	
185	OR	ORTHOPEDIC MANUAL SURGICAL INSTRUMENT	1	Y	888.4540	HXK	
186	PM	CABLE, ELECTRODE	1	Y	888.4540	LXH	
187	PM	JOINT, SHOULDER, EXTERNAL LIMB COMPONENT	1	Y	890.1175	IKD	
188	PM	JOINT, HIP, EXTERNAL LIMB COMPONENT	1	Y	890.3420	IQQ	
189	PM	JOINT, KNEE, EXTERNAL LIMB COMPONENT	1	Y	890.3420	ISL	
190	PM	UNIT, WRIST, EXTERNAL LIMB COMPONENT, MECHANICAL	1	Y	890.3420	ISY	
191	RA	SYSTEM, IMAGING, PULSED ECHO, ULTRASONIC	1	Y	890.3420	ISZ	
192	HO	PUMP, INFUSION, IMPLANTED, PROGRAMMABLE	2	N	892.1560	IYO	
193	CV	CATHETERS, TRANSLUMINAL CORONARY ANGIOPLASTY, PERCUTANEOUS & OPERATIVE	3	N		LKK	
194	CV	ELECTRODE, PERCUTANEOUS, CONDUCTION TISSUE ABLATION	3	N		LOX	
195	HO	PUMP, INFUSION, IMPLANTED, NON-PROGRAMMABLE	3	N		LPB	
196	SU	SIZER, MAMMARY, BREAST IMPLANT VOLUME	3	N		MDY	
197	HO	DEVICE, NEEDLE DESTRUCTION		N		MRD	
198				N		MTV	
199		<i>** Indicates that some products within the product code are 510 (K) exempt, while others are not.</i>					

ATTACHMENT O

	A	B	C	D	E	F
1	Devices Labeled for Single-Use that AMDR Companies May Begin Reprocessing in the Near Future					
2	Medical Specialty	Device Name	Class	510k Exempt (yes/no)	Regulation Number	ProCode
3	AN	FORCEPS, TUBE INTRODUCTION				
4	CV	CATHETER, CONTINUOUS FLUSH	1	Y	868.5780	BWB
5	CV	CATHETER, FLOW DIRECTED	2	N	870.1210	KRA
6	CV	CANNULA, CATHETER	2	N	870.1240	DYG
7	NE	GUIDE, WIRE, CATHETER, NEUROVASCULATURE	2	N	870.1300	DQR
8	CV	INTRODUCER, CATHETER	2	N	870.1330	MOF
9	CV	OCCLUDER, CATHETER TIP	2	N	870.1340	DYB
10	CV	STYLET, CATHETER	2	N	870.1370	DQT
11	CV	INJECTOR AND SYRINGE, ANGIOGRAPHIC	2	N	870.1380	DRB
12	CV	CABLE, TRANSDUCER AND ELECTRODE, PATIENT, (INCLUDING CONNECTOR)	2	N	870.1650	DXT
13	CV	CLIP, VASCULAR	2	N	870.2900	DSA
14	CV	CLIP, VENA-CAVA	2	N	870.3250	DSS
15	CV	TUBING, PUMP, CARDIOPULMONARY BYPASS	2	N	870.3260	DST
16	DE	CURETTE, OPERATIVE	2	N	870.4390	DWE
17	DE	CURETTE, ENDODONTIC	1	Y	872.4565	EKE
18	DE	CURETTE, SURGICAL, DENTAL	1	Y	872.4565	EKT
19	DE	CHISEL, BONE, SURGICAL	1	Y	872.4565	EMK
20	DE	CHISEL, OSTEOTOME, SURGICAL	1	Y	872.4565	EML
21	DE	CURETTE, PERIODONTIC	1	Y	872.4565	EMM
22	DE	LIGHT, FIBER OPTIC, DENTAL	1	Y	872.4565	EMS
23	DE	LIGHT, OPERATING, DENTAL	1	Y	872.4620	EAY
24	DE	LIGHT, SURGICAL HEADLIGHT	1	Y	872.4630	EAZ
25	DE	EXTERNAL MANDIBULAR FIXATOR AND/OR DISTRACTOR	1	Y	872.4630	EBA
26	DE	BAND, MATERIAL, ORTHODONTIC	2	N	872.4760	MQN
27	DE	WIRE, ORTHODONTIC	1	Y	872.5410	DYO
28	DE	TUBE, ORTHODONTIC	1	Y	872.5410	DZC
29	DE	BAND, ELASTIC, ORTHODONTIC	1	Y	872.5410	DZD
30	DE	BAND, PREFORMED, ORTHODONTIC	1	Y	872.5410	ECI
31	DE	CLAMP, WIRE, ORTHODONTIC	1	Y	872.5410	ECM
32	DE	SPRING, ORTHODONTIC	1	Y	872.5410	ECN
33	EN	SET, FILLIFORM, EUSTACHIAN	1	Y	872.5410	ECO
34	EN	CHISEL, MIDDLE-EAR	1	Y	874.4175	KBY
			1	Y	874.4420	JYE

	A	B	C	D	E	F
			1	Y	874.4420	JYF
35	EN	CLAMP, OSSICLE HOLDING	1	Y	874.4420	JYG
36	EN	CURETTE, EAR	1	Y	874.4420	JYH
37	EN	EXCAVATOR, EAR	1	Y	874.4420	JYI
38	EN	GAUGE, MASTOID	1	Y	874.4420	JYJ
39	EN	GAUGE, MEASURING	1	Y	874.4420	JYL
40	EN	HOOK, MICROSURGICAL EAR	1	Y	874.4420	JYM
41	EN	INSERTER, MYRINGOTOMY TUBE	1	Y	874.4420	JYN
42	EN	INSERTER, SACCULOTOMY TACK	1	Y	874.4420	JYO
43	EN	KNIFE, EAR	1	Y	874.4420	JYP
44	EN	KNIFE, MYRINGOTOMY	1	Y	874.4420	JYQ
45	EN	LOOP, WIRE	1	Y	874.4420	JYR
46	EN	NIPPER, MALLEUS	1	Y	874.4420	JYS
47	EN	PERFORATOR, EAR-LOBE	1	Y	874.4420	JYT
48	EN	PICK, MICROSURGICAL EAR	1	Y	874.4420	JYW
49	EN	PRESS, VEIN	1	Y	874.4420	JYX
50	EN	PUNCH, ATTIC	1	Y	874.4420	JYY
51	EN	RASP, EAR	1	Y	874.4420	JYZ
52	EN	ROD, MEASURING EAR	1	Y	874.4420	JZA
53	EN	RONGEUR, MASTOID	1	Y	874.4420	JZC
54	EN	SEARCHER, MASTOID	1	Y	874.4420	JZD
55	EN	SNARE, EAR	1	Y	874.4420	JZE
56	EN	SPOON, EAR	1	Y	874.4420	JZF
57	EN	TUBE, EAR SUCTION	1	Y	874.4420	JZY
58	EN	KNIFE, LARYNGEAL	1	Y	874.4420	JZZ
59	EN	SAW, LARYNGEAL	1	Y	874.4420	KA
60	EN	SET, LARYNGEAL INJECTION	1	Y	874.4420	KAC
61	EN	TUBE, LARYNGECTOMY	1	Y	874.4420	KAD
62	EN	ELEVATOR, ENT	1	Y	874.4420	KAE
63	EN	FORCEPS, ENT	1	Y	874.4420	KAH
64	EN	MICRORULE, ENT	1	Y	874.4420	KAI
65	EN	MIRROR, ENT	1	Y	874.4420	KAJ
66	EN	MOBILIZER, ENT	1	Y	874.4420	KAK
67	EN	PROBE, ENT	1	Y	874.4420	KAL
68	EN	RETRACTOR, ENT	1	Y	874.4420	KA
69	EN	CURETTE, ETHMOID	1	Y	874.4420	KAP
70	EN	CURETTE, NASAL				

	A	B	C	D	E	F
			1	Y	874.4420	KAQ
71	EN	GOUGE, NASAL, ENT	1	Y	874.4420	KAR
72	EN	IRRIGATOR, SINUS	1	Y	874.4420	KAT
73	EN	PERFORATOR, ANTRUM	1	Y	874.4420	KAW
74	EN	PUNCH, ANTRUM	1	Y	874.4420	KAX
75	EN	PUNCH, ETHMOID	1	Y	874.4420	KAY
76	EN	PUNCH, NASAL	1	Y	874.4420	KAZ
77	EN	RASP, FRONTAL-SINUS	1	Y	874.4420	KBA
78	EN	RASP, NASAL	1	Y	874.4420	KBB
79	EN	RONGEUR, NASAL	1	Y	874.4420	KBC
80	EN	SAW, NASAL	1	Y	874.4420	KBE
81	EN	SNARE, NASAL	1	Y	874.4420	KBF
82	EN	TREPHINE, SINUS	1	Y	874.4420	KBH
83	EN	ADENOTOME	1	Y	874.4420	KBJ
84	EN	CURETTE, ADENOID	1	Y	874.4420	KBK
85	EN	CURETTE, SALPINGEAL	1	Y	874.4420	KBL
86	EN	DEPRESSOR, METAL TONGUE, ENT	1	Y	874.4420	KBM
87	EN	DISSECTOR, TONSIL	1	Y	874.4420	KBN
88	EN	GAG, MOUTH	1	Y	874.4420	KBO
89	EN	GUILLOTINE, TONSIL	1	Y	874.4420	KBP
90	EN	HOOK, TONSIL SUTURING	1	Y	874.4420	KBR
91	EN	NEEDLE, TONSIL SUTURING	1	Y	874.4420	KBS
92	EN	PUNCH, ADENOID	1	Y	874.4420	KBT
93	EN	PUNCH, TONSIL	1	Y	874.4420	KBW
94	EN	SCREW, ORAL	1	Y	874.4420	KBX
95	EN	SCREW, TONSIL	1	Y	874.4420	KBZ
96	EN	SNARE, TONSIL	1	Y	874.4420	KCA
97	EN	TONSILLECTOME	1	Y	874.4420	KCB
98	EN	TUBE, TONSIL SUCTION	1	Y	874.4420	KCC
99	EN	BISTOURY, TRACHEAL	1	Y	874.4420	KCD
100	EN	BOUGIE, ESOPHAGEAL, ENT	1	Y	874.4420	KCF
101	EN	DILATOR, ESOPHAGEAL, ENT	1	Y	874.4420	KCG
102	EN	DILATOR, TRACHEAL	1	Y	874.4420	KCH
103	EN	HOOK, TRACHEAL	1	Y	874.4420	KTE
104	EN	TROCAR, ENT	1	Y	874.4420	KTF
105	EN	PUNCH, ENT	1	Y	874.4420	KTG
106	EN	KNIFE, ENT				

	A	B	C	D	E	F
107	EN	TRACHEOTOME	1	Y	874.4420	LJW
108	EN	INSTRUMENT, ENT MANUAL SURGICAL	1	Y	874.4420	LRC
109	EN	CURETTE, BIOPSY, BRONCHOSCOPE (RIGID)	2	N	874.4680	JEL
110	GU	ILLUMINATOR, FIBEROPTIC, FOR ENDOSCOPE	2	N	876.1500	FFS
111	GU	CORD, ELECTRIC, FOR ENDOSCOPE	2	N	876.1500	FFZ
112	GU	ENDOSCOPE, FIBER OPTIC	2	N	876.1500	GDB
113	GU	SCISSORS FOR CYSTOSCOPE	2	N	876.1500	KGD
114	CV	ANGIOSCOPE	2	N	876.1500	LYK
115	GU	SNARE, RIGID SELF-OPENING	2	N	876.4300	FDJ
116	GU	CATHETER, MALECOT	2	N	876.5090	FEW
117	GU	CATHETER AND TUBE, SUPRAPUBIC	2	N	876.5090	FEZ
118	GU	CATHETER, SUPRAPUBIC (AND ACCESSORIES)	2	N	876.5090	KOB
119	GU	CATHETER, URETERAL, GASTRO-UROLOGY	2	N	876.5130	EYB
120	GU	CATHETER, UPPER URINARY TRACT	2	N	876.5130	EYC
121	GU	ADAPTOR, URETERAL CATHETER	1	Y	876.5130	EYI
122	GU	HOLDER, URETERAL CATHETER	1	Y	876.5130	FYJ
123	GU	CONNECTOR, URETERAL CATHETER	1	Y	876.5130	EYK
124	GU	STYLET FOR CATHETER, GASTRO-UROLOGY	1	Y	876.5130	EZB
125	GU	CATHETER, COUDE	2	N	876.5130	EZC
126	GU	CATHETER, STRAIGHT	2	N	876.5130	EZD
127	GU	CATHETER, DOUBLE LUMEN FEMALE URETHROGRAPHIC	2	N	876.5130	FGH
128	GU	CATHETER, UROLOGICAL	2	N	876.5130	KOD
129	GU	FILIFORM AND FILIFORM FOLLOWER	1	Y	876.5520	FBW
130	GU	CATHETER, HEMODIALYSIS, NON-IMPLANTED	2	N	876.5540	MPB
131	GU	CATHETER, PERITONEAL DIALYSIS, SINGLE USE	2	N	876.5630	FKO
132	SU	CATHETER, CONTINUOUS IRRIGATION	1	Y	878.4200	GBQ
133	SU	CATHETER, IRRIGATION	1	Y	878.4200	GBX
134	SU	NEEDLE, GASTRO-UROLOGY	1	Y	878.4800	FHR
135	SU	TRAY, SURGICAL, INSTRUMENT	1	Y	878.4800	FSM
136	SU	LOUPE, DIAGNOSTIC/SURGICAL	1	Y	878.4800	FSP
137	SU	EXPANDER, SURGICAL, SKIN GRAFT	1	Y	878.4800	FZW
138	SU	GUIDE, SURGICAL, INSTRUMENT	1	Y	878.4800	FZX
139	SU	HAMMER, SURGICAL	1	Y	878.4800	FZY
140	SU	NEEDLE, ASPIRATION AND INJECTION, DISPOSABLE	1	Y	878.4800	GAA
141	SU	NEEDLE, SUTURING, DISPOSABLE	1	Y	878.4800	GAB
142	SU	STYLET, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GAH

	A	B	C	D	E	F
143	SU	STRIPPER, VEIN, REUSABLE	1	Y	878.4800	GAI
144	SU	RETAINER, SURGICAL	1	Y	878.4800	GCZ
145	SU	GUIDE, NEEDLE, SURGICAL	1	Y	878.4800	GDF
146	SU	NEEDLE, SUTURING, REUSABLE	1	Y	878.4800	GDL
147	SU	NEEDLE, ASPIRATION AND INJECTION, REUSABLE	1	Y	878.4800	GDM
148	SU	KNIFE, AMPUTATION	1	Y	878.4800	GDN
149	SU	APPLIER, SURGICAL, CLIP	1	Y	878.4800	GDO
150	SU	CANNULA, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GEA
151	SU	BRUSH, SCRUB, OPERATING-ROOM	1	Y	878.4800	GEC
152	SU	BRUSH, DERMABRASION, MANUAL	1	Y	878.4800	GED
153	SU	ELEVATOR, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GEG
154	SU	CARRIER, LIGATURE	1	Y	878.4800	GEJ
155	SU	FILE, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GEO
156	SU	FILE, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GEO
157	SU	OSTEOTOME, MANUAL	1	Y	878.4800	GFI
158	SU	MALLET, SURGICAL, GENERAL & PLASTIC SURGERY	1	Y	878.4800	GFJ
159	SU	INSTRUMENT, LIGATURE PASSING AND KNOT TYING	1	Y	878.4800	HCF
160	SU	HEMOSTAT	1	Y	878.4800	HRQ
161	SU	PLIERS, SURGICAL	1	Y	878.4800	HTC
162	SU	ELEVATOR	1	Y	878.4800	HTE
163	SU	GUIDE	1	Y	878.4800	HXH
164	SU	MALLET	1	Y	878.4800	HXL
165	SU	FORCEPS, WIRE HOLDING	1	Y	878.4800	HYA
166	SU	CANNULA, EAR	1	Y	878.4800	JYC
167	SU	CANNULA, SINUS	1	Y	878.4800	KAM
168	SU	CHISEL, NASAL	1	Y	878.4800	KAN
169	SU	CANNULAE, BRONCHIAL	1	Y	878.4800	KCE
170	SU	KIT, SURGICAL INSTRUMENT, DISPOSABLE	1	Y	878.4800	KDD
171	SU	NEEDLE, TUMOR LOCALIZATION	1	Y	878.4800	MIJ
172	SU	DEVICE, PERCUTANEOUS, BIOPSY	1	Y	878.4800	MJG
173	SU	HEAD, SURGICAL, HAMMER	1	Y	878.4820	GFB
174	SU	BRUSH, DERMABRASION	1	Y	878.4820	GFE
175	SU	TOURNIQUET, GASTRO-UROLOGY	1	Y	878.5900	EYR
176	HO	RESTRAINT, PATIENT, CONDUCTIVE	1	N	880.6760	BRT
177	HO	RESTRAINT, PROTECTIVE	1	N	880.6760	FMQ
178	NE	ELECTRODE, NEEDLE	2	N	882.1350	GXZ

	A	B	C	D	E	F
179	NE	PROBE, RADIOFREQUENCY LESION				
180	OB	BRUSH, ENDOMETRIAL	2	N	882.4725	GXI
181	OB	CURETTE, SUCTION, ENDOMETRIAL (AND ACCESSORIES)	3	N	884.1100	HFE
182	OB	HOOK, FIBROID, GYNECOLOGICAL	2	N	884.1175	HHK
183	OB	SPECULUM, VAGINAL, METAL	1	Y	884.4520	HDE
184	OB	SPECULUM, VAGINAL, METAL, FIBEROPTIC	1	Y	884.4520	HDF
185	OB	RETRACTOR, VAGINAL	1	Y	884.4520	HDG
186	OB	PACKER, UTERINE	1	Y	884.4520	HDL
187	OB	PELVIMETER, EXTERNAL	1	Y	884.4520	HDM
188	OB	CLAMP, UTERINE	1	Y	884.4520	HER
189	OB	APPLICATOR, VAGINAL	1	Y	884.4520	HGC
190	OB	INSTRUMENT, MANUAL, GENERAL OBSTETRIC-GYNECOLOGIC	1	Y	884.4520	HGD
191	OB	CURETTE, UTERINE	1	Y	884.4520	KOH
192	OB	FORCEPS, SURGICAL, GYNECOLOGICAL	1	Y	884.4530	HCY
193	OB	DILATOR, CERVICAL, FIXED SIZE	2	N	884.4530	HCZ
194	OB	KNIFE, CERVICAL CONE	1	Y	884.4530	HDQ
195	OB	CLAMP, UMBILICAL	2	N	884.4530	HDZ
196	OB	CLAMP, CIRCUMCISION	2	N	884.4530	HFZ
197	OP	DEVICE, FIXATION, AC-POWERED, OPHTHALMIC	2	N	884.4530	HFX
198	OP	BURR, CORNEAL, BATTERY-POWERED	1	Y	886.1300	HPL
199	OP	BURR, CORNEAL, AC-POWERED	1	N	886.4070	HOG
200	OP	ENGINE, TREPHINE, ACCESSORIES, BATTERY-POWERED	1	N	886.4070	HQS
201	OP	ENGINE, TREPHINE, ACCESSORIES, AC-POWERED	1	N	886.4070	HRF
202	OP	UNIT, CAUTERY, THERMAL, AC-POWERED	1	N	886.4070	HRG
203	OP	UNIT, CAUTERY, THERMAL, BATTERY-POWERED	2	N	886.4115	HQO
204	OP	INSTRUMENT, VITREOUS ASPIRATION AND CUTTING, BATTERY-POWERED	2	N	886.4115	HQP
205	OP	INSTRUMENT, VITREOUS ASPIRATION AND CUTTING, AC-POWERED	2	N	886.4150	HKP
206	OP	SPATULA, OPHTHALMIC	2	N	886.4150	HQE
207	OP	SNARE, ENUCLEATING	1	Y	886.4350	HND
208	OP	SCISSORS, OPHTHALMIC	1	Y	886.4350	HNE
209	OP	HOOK, OPHTHALMIC	1	Y	886.4350	HNF
210	OP	FORCEPS, OPHTHALMIC	1	Y	886.4350	HNQ
211	OP	CURETTE, OPHTHALMIC	1	Y	886.4350	HNR
212	OP	CLAMP, MUSCLE, OPHTHALMIC	1	Y	886.4350	HNZ
213	OP	BURR, CORNEAL, MANUAL	1	Y	886.4350	HOB
214	OP	TREPHINE, MANUAL, OPHTHALMIC	1	Y	886.4350	HOF
			1	Y	886.4350	HRH

	A	B	C	D	E	F
215	OR	ACCESSORIES, ARTHROSCOPIC	1	Y	888.1100	NBH
216	OR	STRIPPER, SURGICAL	1	Y	888.4540	HRT
217	OR	FILE	1	Y	888.4540	HTP
218	OR	BROACH	1	Y	888.4540	HTQ
219	OR	IMPACTOR	1	Y	888.4540	HWA
220	OR	EXTRACTOR	1	Y	888.4540	HWB
221	OR	STARTER, BONE SCREW	1	Y	888.4540	HWD
222	OR	CORKSCREW	1	Y	888.4540	HWI
223	OR	AWL	1	Y	888.4540	HWJ
224	OR	SET, HOLLOW MILL	1	Y	888.4540	HWL
225	OR	INSTRUMENT, COMPRESSION	1	Y	888.4540	HWN
226	OR	SKID, BONE	1	Y	888.4540	HWO
227	OR	PUNCH, FEMORAL NECK	1	Y	888.4540	HWP
228	OR	PASSER	1	Y	888.4540	HWQ
229	OR	DRIVER, PROSTHESIS	1	Y	888.4540	HWR
230	OR	PROBE	1	Y	888.4540	HXB
231	OR	WRENCH	1	Y	888.4540	HXC
232	OR	FORK	1	Y	888.4540	HXE
233	OR	TAMP	1	Y	888.4540	HXG
234	OR	PASSER, WIRE, ORTHOPEDIC	1	Y	888.4540	HXI
235	OR	APPLIER, CERCLAGE	1	Y	888.4540	HXN
236	OR	PUSHER, SOCKET	1	Y	888.4540	HXO
237	OR	INSTRUMENT, BENDING OR CONTOURING	1	Y	888.4540	HXP
238	OR	CRIMPER, PIN	1	Y	888.4540	HXQ
239	OR	TWISTER, WIRE	1	Y	888.4540	HXS
240	OR	BENDER	1	Y	888.4540	HXW
241	OR	SCREWDRIVER	1	Y	888.4540	HXX
242	OR	BRACE, DRILL	1	Y	888.4540	HXY
243	OR	CUTTER, WIRE	1	Y	888.4540	HXZ
244	OR	POSITIONER, SOCKET	1	Y	888.4540	KIL
245	PM	CABLE	1	Y	890.3420	ISN
246	SU	INSTRUMENT, DISPOSAL, SURGICAL (SHARPS)		N		KDB
247	SU	INSTRUMENT, ULTRASONIC SURGICAL		N		LFL
248	CV	CATHETER, ANGIOPLASTY, PERIPHERAL, TRANSLUMINAL		N		LIT
249	NE	CATHETER, STEERABLE CEREBROVASCULAR	3	N		LJA
250	NE	LASER, NEUROSURGICAL	3	N		LKW

	A	B	C	D	E	F
251	CV	LEGGING, COMPRESSION, NON-INFLATABLE		N		LLK
252	CV	DEVICE, ANGIOPLASTY, LASER, CORONARY	3	N		LPC
253	GU	DISLODGER, STONE, BILIARY		Y		LQR
254	SU	PUNCH, SURGICAL		N		LRY
255	OR	ACCESSORIES, FIXATION, SPINAL INTERLAMINAL		N		LYP
256	OR	ACCESSORIES, FIXATION, SPINAL INTERVERTEBRAL BODY		N		LYQ
257	OR	FIXATION ACCESSORY		N		LYT
258	OB	CATHETERS, SALPINGOGRAPHY		N		MOV
259	OR	CAST,STOCKING,ANTI-MICROBIALS		Y		MTT

ATTACHMENT P



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 9 1999

Stephen D. Terman, Esq.
Olsson, Frank and Weeda, P.C.
Attorneys At Law
Suite 400
1400 Sixteenth Street, N.W.
Washington, D.C. 20036-2220

Dear Mr. Terman:

This letter supercedes the October 19, 1998 letter ("October 19 letter") I issued to you in response to your August 20, 1998 letter, requesting a FDA statement on the legal status of the reprocessing of single use devices. The current letter is written to correct erroneous information provided in the second paragraph of the October 19 letter. That letter stated that "... reprocessing of devices labeled for single use is lawful in the United States provided that the reprocessing firm complies fully with all regulatory requirements currently imposed on them." This is not the case. Therefore, the October 19 letter should be destroyed and all references to that letter should be discontinued. The following paragraph represents the Agency's position on the legality of single use reprocessing and replaces the second paragraph of the October 19 letter.

Third-party reprocessing of devices labeled for single use is unlawful unless those engaged in this practice comply with all regulatory requirements for manufacturers, including premarket notification requirements. However, FDA has exercised and will continue to exercise regulatory discretion for all premarket notification requirements, until a new FDA reprocessing position is adopted. The most significant regulatory requirement, at this time, is compliance with the newly developed Quality System regulation. That regulation requires appropriate manufacturing and quality assurance controls over all the firm's reprocessing operations including cleaning, disinfection, packaging, labeling, sterilization, distribution, etc. Third-party reproducers are subject to FDA inspection and enforcement actions will not be taken against them or their products unless FDA has determined that 1) the firm is out of compliance with current applicable regulatory requirements (with regulatory discretion for all premarket notification requirements, until a new FDA reprocessing position is adopted), or 2) the firm's products represent a danger to health.

If you have any questions regarding this letter, please contact me at 301-594-4646

Sincerely yours,

Larry Spears
Director
Division of Enforcement III
Office of Compliance
Center for Devices and
Radiological Health

Enclosure: October 19, 1998 letter to Stephen D. Terman



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration
Office of Clinical Standards & Quality

7500 Security Boulevard
Baltimore, MD 21244-18

Josephine M. Torrente, Esq.
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, N.W.
Suite 1200
Washington, D.C. 20005-5929

Dear Ms. Torrente:

This is in response to your letter of August 16, 1999, requesting clarification of the Health Care Financing Administration's (HCFA) policy regarding Medicare coverage of reprocessed medical devices intended for single use only.

Our position with respect to reprocessed medical devices remains the same as that which was stated in our June 18 letter to Mr. Barry D. Alexander, Esq. of Epstein, Becker & Green, P.C. That is, HCFA will allow reprocessing of medical devices originally labeled for single use only if it is lawful under Food and Drug Administration (FDA) statutes, regulations, and policy guidelines. If the FDA's current position is that reprocessing of single-use medical devices is unlawful absent premarket notification, these devices will not be covered under Medicare.

I trust this letter fully addresses your request. If you have any further questions, you may contact me at (410) 786-7176.

Sincerely,

/s/

Grant P. Bagley, M.D.
Director
Coverage and Analysis Group

cc: Barry D. Alexander, Esq.