AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

September 26, 2011

By Electronic Submission

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

Re: Docket No. FDA-2011-N-0294 Reprocessing of Reusable Medical Devices

Dear Sir or Madam:

The Association of Medical Device Reprocessors (AMDR)[1] respectfully submits the following comments in response to the notice published in the *Federal Register* by the Food and Drug Administration (FDA) on July 28, 2011, soliciting input on the Reprocessing of Reusable Medical Devices.[2] AMDR commends FDA for soliciting input on this important issue, underscoring the agency's commitment to advancing patient safety with regard to reprocessed medical devices.

On August 1, 2011, AMDR also submitted comments to FDA on the agency's *Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* (Docket FDA-2011-D-0293). Both dockets solicit input on the reprocessing of *reusable* devices; however, AMDR believes that our members' experience with validated methods for reprocessing "single-use" devices (SUD) is applicable to FDA's current effort to address factors affecting the reprocessing of reusable devices, including reprocessing quality, device design, reprocessing methodologies, validation methodologies, and healthcare facility best practices.

AMDR shares the agency's commitment to ensuring that *all* reprocessed medical devices are safe and effective. Patients and clinicians expect medical devices to be processed/reprocessed properly, meaning no increased risks to patients. AMDR believes that all manufacturers – which, by definition, includes third-party reprocessors – should be held to the highest standards when reprocessing or providing instructions for reprocessing medical devices – regardless of how the device is labeled *(e.g.*, reusable, single-use, etc.).

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[1] AMDR is a trade association representing the legal, regulatory and legislative interests of FDA-regulated, third-party reprocessors of medical devices labeled by the original manufacturer as for "single-use." It is estimated that AMDR members perform approximately 95 percent of the third-party reprocessing in the United States today. AMDR's members serve over 3,000 U.S. hospitals, including 16 of the 17 Honor Roll hospitals according to U.S. News & World Report 2011-12. AMDR's members also serve 9 out of the top 10 Best Hospitals in the following specialties: Cardiology and Heart Surgery; Ear, Nose and Throat; Diabetes and Endocrinology; Gastroenterology; and Geriatrics.

[2] 76 Fed. Reg. 45268 (July 28, 2011).

We provide the following input and comments for consideration.

SUD Reprocessors are Stringently Regulated by FDA

In AMDR's August 1, 2011 comments, we highlighted that FDA's experience in regulating the reprocessors of SUDs applies to its current efforts to identify factors affecting the reprocessing of reusable devices. As we explained, FDA already has in place a long-standing, stringent regulatory framework for reprocessors of SUDs. The result of FDA's regulatory requirements for SUD reprocessors is that reprocessed SUDs are as safe and effective as original devices and pose no increased risk to patients. In addition to the decade of safe clinical use, both FDA and the independent U.S. Government Accountability Office (GAO) have concluded that there is no evidence of harm to patients from FDA-regulated reprocessed SUDs.[3]

AMDR is proud to have worked with FDA to ensure that our reprocessed SUDs are safe and effective for clinicians and patients. The leadership demonstrated by FDA in choosing to legitimize the third-party SUD reprocessing industry through regulation is now looked at as a model. AMDR believes that FDA is again poised to demonstrate such leadership with these new activities aimed at encouraging proper reprocessing of reusable devices.

SUD Reprocessors Are Subject to Stringent, Premarket Cleaning, Sterilization and Functional Testing Validation Data Requirements

AMDR wishes to respond to the comments submitted by the Advanced Medical Technology Association (AdvaMed), the association representing the original equipment manufacturers (OEM). Contrary to arguments presented by AdvaMed, SUD reprocessors are not subject to lower standards than the agency proposes to require of OEMs with regard to premarket cleaning data. To the contrary, third-party SUD reprocessors already perform reprocessing validations that are consistent with the validation methods proposed in FDA's Draft Guidance (*Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*). Importantly, this validation data is generally subject to premarket review.

Pursuant to FDA's guidance, *Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices, as authorized by the Medical Device User Fee and Modernization Act of 2002*, SUD reprocessors are required to submit to FDA, on a premarket basis, validation data on cleaning, sterilization, and functional performance – demonstrating that

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[3] U.S. Government Accountability Office, GAO-08-147, *Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk* (January 2008), at 14-19 ("After reviewing the available evidence—including FDA's process for identifying and investigating device-related adverse events reported to involve reprocessed SUDs, peer-reviewed studies published since 2000, and the results of our and FDA's consultations with hospital representatives—we found no reason to question FDA's analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs. That is, the available information regarding safety, while not providing a rigorous safety comparison between reprocessed SUDs and other devices, does not indicate that reprocessed SUDs currently in use pose an increased safety threat") (emphasis added).

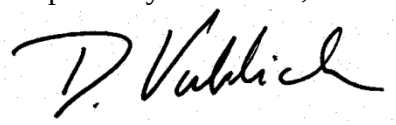
the reprocessed SUD remains substantially equivalent to the predicate device after the maximum number of times the device has been reprocessed.[4]

In applying these increased data requirements, FDA relied in large part on AAMI's Technical Information Report (TIR) 30[5]. For example, consistent with the recommendations in TIR 30, third-party reprocessors are required to conduct worst-case cleaning validations, employ artificial or native test soils to inoculate devices as part of cleaning validations, and test for meaningful levels of clinically relevant soil. FDA now recommends that such validations be undertaken by OEMs to validate the proper reprocessing of their reusable devices. FDA began requiring SUD reprocessor compliance with the principles outlined in TIR 30 on a *premarket basis* as far back as 2004. As such, validation data is provided as part of most SUD reprocessor premarket notifications. Such validation submission requirements do not exist currently on a *premarket basis* for reusable devices.

AMDR commends FDA for strengthening the premarket validation requirements for OEMs of reusable devices through its Draft Guidance. However, AMDR encourages the agency to not only require that OEMs include validated labeling instructions in their premarket notifications *but also* require OEMs to provide the underlying cleaning, sterilization, and functional performance validation data to FDA on a premarket basis. As mentioned above, reprocessors of SUDs have been required to provide such validation data on a premarket basis since 2004. Such an approach would harmonize the treatment of reprocessed devices (regardless of whether they are single-use or reusable) and, more importantly, help ensure that potential safety issues stemming from inadequate validations are reviewed by the agency before problems arise in the clinical setting.

On behalf of AMDR, we appreciate the agency's time and attention to these matters. Thank you.

Respectfully Submitted,



Daniel J. Vukelich, Esq.
President
Association of Medical Device Reprocessors

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[4] The Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessing Single-Use Medical Devices (Sept. 25, 2006).

[5] In fact, AMDR holds a voting seat on AAMI's technical committee, "Cleaning of Reusable Medical Devices Working Group 93 (for TIR 30),"[5] underscoring the importance of the TIR to the nation's third-party SUD reprocessing industry. *See* Association for the Advancement of Medical Instrumentation (AAMI), Technical Information Report: A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices (AAMI TIR 30; 2011). Note, a revised TIR is expected to be issued in 2011, thus the new date.