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U.S. Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fisher's Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. 02N-0534

To Whom It May Concern:

Alliance Medical Corporation, a leading reprocessor of used single use devices, appreciates the opportunity to offer comment in the matter of implementing Section 302 of the Medical Device User Fee and Modernization Act of 2002, specifically as it pertains to identifying the critical reprocessed Class I, 510(k)-exempt devices for which a premarket notification should be required.

We are aware, and to an extent understand, that the original manufacturers of virtually every Class I, 510(k) exempt device that is commonly reprocessed is soliciting FDA to require a premarket notification on these devices. They have perhaps calculated the costs associated with developing a submission, and deigned the whole effort not cost-effective for a reprocessor. They presume to use this provision of law to protect their income, not the public.

Toward that end, there is a very long list of devices they are suggesting require a premarket submission. The issue for FDA, however, is one of public health. To wit., is there a public health basis to remove the premarket exemption for these devices?

Alliance Medical Corporation offers our comments on the following devices, suggested by AdvaMed for exemption removal:

Disposable Manual Arthroscopic Accessories (21 CFR 888.1100):

This category is comprised of a diverse group of devices. Many of the devices are both very simple in design and construction and low risk (meaning a device failure or malfunction is very unlikely and an associated patient adverse event is only a remote possibility). Such devices do not require a 510(k) for reprocessing in order to enhance or ensure the public health.

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The general controls for medical devices, particularly the Quality System regulation, provide reasonable assurance that the reprocessed device is both safe and effective. These requirements include provisions for process validation and control of non-conforming product, which are sufficient to ensure these devices, when reprocessed, are safe and effective.

Surgical Burs and Blades (21 CFR 878.4820):

This category of devices encompasses a large group of devices; however, there is a common reality for all devices in this category: the devices are durable (usually constructed of stainless steel, but sometimes also having a diamond cutting edge), and have no features that make the devices difficult to clean. For much the same reason, these devices are easy to sterilize with virtually no risk of sterilant gas residue.

These devices do not experience severe stress during use that make them likely to fail in subsequent use. The design of the devices allow the edgeforms to be easily restored without risk of altering the structure or function of the device.

These devices are commonly labeled for re-use in other countries. There is nothing unique about the devices sold in the U.S., nor are there any geographically-limited phenomena associated with use within the boundaries of this country, causing these devices to have a higher risk of patient adverse event when reprocessed.

There is no public health basis for granting a request that these devices be removed from 510(k) exemption.

Disposable Drill Bits (21 CFR 878.4820):

These surgical instruments are typically very durable yet low-risk devices with no difficult to clean features. Most commonly, these are made of stainless steel or another high robust material. With very few exceptions, the design of the devices are very simple, such that the devices can be easily cleaned and sterilized.

Initial use of the device may lead or contribute to a slight bend; however, such devices can be easily detected with test or visual verification standards.

Sterilization of these devices present no unusual challenges, and sterilant gas residual is rarely excessive.

These devices may be sold in other jurisdictions as re-useable products.

There is no public health basis for granting a request that these devices be removed from 510(k) exemption.

Non-electric biopsy forceps (21 CFR 876.1075):

Boston Scientific Corporation, the parent company of Microvasive (a manufacturer of non-electric biopsy forceps) filed a Citizens' Petition requesting the 510(k) exemption for these devices be removed when the device is reprocessed. That petition was denied. Since then, nothing has changed. There have been no reports of patient death or adverse event associated with reprocessed devices. The device design has not changed appreciably. The intended use of the device has not been revised. The instructions for use of the device has not changed.

Nothing has changed. Neither have the methods used by Alliance Medical Corporation to clean, test and sterilize these devices. We conclude, as must FDA, that there is no public health benefit to requiring a reprocessed device 510(k) for these devices.

Although AdvaMed has not submitted a position statement on heart stabilizers and positioners, Alliance Medical Corporation respectfully suggests these devices should be removed from 510(k) exemption. These devices, used during certain open heart procedures, may come in contact with the heart. If bacterial cell remnants remain following cleaning, a pyrogenic reaction may develop leading to adverse patient outcome. Consequently, there is a public health reason for the technical file on reprocessing be reviewed prior to allowing the reprocessing service to be commercialized.

We appreciate the opportunity to provide comment on this very important issue, and trust FDA will continue to establish good public health policy with it's decision on which, if any, currently exempt devices will require a premarket notification for reprocessing.

Sincerely,

Don Selvey, Vice President
Regulatory Affairs and Quality Assurance
Alliance Medical Corporation