MEDICAL DEVICE MANUFACTURERS ASSOCIATION
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January 23, 2003

0548 '03 FEB 10 A9:28

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Attn: Bill Sutton
1350 Piccard Drive
Rockville, Maryland 20850

Re: Docket No. 02N-0534

Dear Sir or Madam:

The Medical Device Manufacturers Association (MDMA) respectfully submits these comments requesting the Commissioner of the Food and Drug Administration (FDA) to list reprocessed, single-use non-electric biopsy forceps as critical, single-use devices for which the exemption from premarket review pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act should be terminated in accordance with Title III, Section 301(b)(2) of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).[1] MDMA is the national voice for the entrepreneurial sector of the medical device industry, representing over 160 companies. We believe the reuse of single-use non-electric biopsy forceps is an unsafe practice that puts patients at risk of an unnecessary injury or infection from the unapproved reprocessing and reuse of the original single-use products. Industry sponsored studies, combined with the FDA's own studies, demonstrates that the reprocessing and reuse of single-use biopsy forceps raises questions of safety and effectiveness that must be answered by requiring premarket submissions.

Biopsy forceps are designed and manufactured for use in a single patient prior to being discarded. Because of the unique design features of these devices, attempts to clean and use them on multiple patients present a hazard to public health. These devices contain many areas that are difficult to access, such as long and narrow lumens, crevices, coils and joints, reinforcing meshes and rough, porous or occluded surfaces. These inaccessible areas create barriers to cleaning and allow for the collection of organic matter, such as blood, feces, and gastric mucin.

The hazard posed to public health by reprocessing single use biopsy forceps is not hypothetical. Several studies conducted by independent labs reveal that reprocessed single-use biopsy forceps present an increased risk of infection to patients. Specifically, more than 31 percent of reprocessed devices randomly selected from hospital shelves failed the sterility tests and over 94 percent tested positive for the presence of residual tissue. See Boston Scientific

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[1] Non-electric biopsy forceps are classified as exempt Class I medical devices. See 21 C.F.R. § 876.1075(b)(2). Pursuant to FDA's Enforcement Guidance for Reprocessed Single-Use Devices, the reprocessing and reuse of these devices are exempt from premarket review under Section 510(k) of the Federal Food, Drug and Cosmetic Act.

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Corporation's Comments in Support of Listing Reprocessed Single-use, Non-electric Biopsy Forceps as Critical, Single-use Devices Pursuant to Section 301(b)(2) of MDUFMA, dated January 21, 2003. In fact, due to the risk of infection and unacceptable device performance, FDA, in its February 2000 Draft Enforcement Prioritization Guidance, identified reprocessed, single-use biopsy forceps as high-risk devices.

Ethylene oxide gas is the most common method used by reprocessors to sterilize biopsy forceps. However, ethylene oxide sterilization is a bioburden-based method that has significant limitations, including the inability of the gas to penetrate tissue that may remain on the device from previous use. Residual liquid in the lumen of the forceps also interferes with the effectiveness of this method. In studies conducted by the FDA's Office of Science and Technology using three types of single-use gastrointestinal biopsy forceps, researchers found that residual water remained in the devices following a typical cleaning sequence of bleach, ultrasonic bath with detergent and enzyme, and water rinse. This inability to dry adequately the device lumen decreases the effectiveness of sterilization. Thus, even when organic debris can be removed from these devices, the existence of residual water compromises the ability to sterilize them effectively.

Reprocessing and reuse also may affect adversely the performance of single-use non-electric biopsy forceps due to the materials and components that make up the devices. The harsh conditions of reprocessing diminish the performance and structural integrity of these devices. In addition, cleaning attempts that damage these single-use devices can lead to device failure from material fatigue or can compromise device functionality in other ways, such as by reducing their sharpness. If the jaws do not remain sharp, they will be unable to extract tissue samples from the body. The forceps needles also can be dulled by reprocessing methods. Frequently, needles that have been reprocessed will not properly anchor the forceps to the tissue sample and may not effectively attach to the sample for removal. Sterilization methods using heat also may cause the plastic sheath to melt onto the wires inside the forceps. If this occurs, the forceps' collection jaws will not operate properly, and can compromise the effectiveness of the procedure.

MDMA believes that industry-sponsored studies, as well as FDA's own evaluations, raise serious questions about the safety and effectiveness of reprocessed single-use biopsy forceps. The results of these studies should compel the FDA to limit the exemption from premarket notification requirements to non-electric biopsy forceps labeled for single use that are not reprocessed. Accordingly, FDA must list reprocessed, single-use, non electric biopsy forceps pursuant to Section 301(b)(2) of Title III of MDUFMA.

Sincerely,

Mark B. Leahey, Esq.
Executive Director