Boston Scientific

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July 14, 2003

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

Re: Docket No. 03N-0161

Dear Madam or Sir:

Boston Scientific Corporation (BSC) submits these comments in support of the addition of non-electric biopsy forceps to the list of critical, reprocessed single-use devices for which the exemption from premarket review pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act (FFDCA) will be terminated in accordance with Title III, Section 301(b)(2) of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).[1] In a previous Federal Register notice, the Food and Drug Administration (FDA) identified non-electric biopsy forceps as exempt, semi-critical, high risk devices.[2] Because FDA mistakenly classified these devices as "semi-critical," rather than "critical," non-electric biopsy forceps were not included on List I, which is comprised of those devices for which the exemption from premarket notification requirements will be terminated pursuant to Section 301(b)(2) of MDUFMA. FDA has now determined that non-electric biopsy forceps are critical (rather than semi-critical) devices, and has issued this Federal Register notice to correct that designation and revise List I to add this class of devices.

BSC supports FDA's addition of non-electric biopsy forceps to List I. This action is required by the statutory mandates of MDUFMA and is necessary to ensure the safety and effectiveness of reprocessed, single-use non-electric biopsy forceps upon reuse. In these comments, BSC summarizes the bases for classifying non-electric biopsy forceps as "critical" devices under MDUFMA.

Biopsy Forceps Meet the Statutory Definition of Critical Devices

BSC agrees with FDA's conclusion that non-electric biopsy forceps should properly be considered critical devices. MDUFMA defines a critical device as a "device that is intended to contact normally sterile tissues or body spaces during use." A semi-critical device is one "that is intended to contact in-tact mucous membranes and not penetrate normally sterile

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1 *See* 68 Fed. Reg. 38071 (June 26, 2003).

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

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areas of the body." As indicated in the legislative history to MDUFMA and in FDA's Federal Register notice, these classifications reflect the commonly accepted Spaulding classification scheme.[3]

In comments submitted to the FDA docket on February 4, 2003, BSC stated that "[i]n order to accomplish their intended use, single-use, non-electric biopsy forceps must break through the mucosa barrier of the gastrointestinal tract, contact the blood stream and remove a sample of tissue, thus contacting normally sterile tissue or body spaces." BSC explained that endoscopic biopsy, whether of the esophagus or gastrointestinal tract, is indicated for the diagnosis of mucosal abnormalities.[4] Biopsy forceps enter the gastrointestinal (GI) tract through an endoscope which serves to shield the sterile forceps from the non-sterile environment of the GI tract. At the point of use, the forceps are extended from the sheath, the cups are opened, positioned on the esophageal or gastrointestinal mucosal tissue and then closed. The act of closing and pulling on the tissue tears off a specimen of the target tissue. The specimen is then retrieved by bringing the biopsy forceps out through the channel of the endoscope. Thus, based on their indication and use, biopsy forceps penetrate the mucosal barrier of the GI tract and come into contact with normally sterile tissue. Further, in some applications – such as for submucosal tumors – larger-capacity biopsy forceps are used to obtain larger, deeper samples of not only the mucosa but submucosal tissue layers.

Biopsy forceps therefore clearly satisfy the Spaulding definition of critical devices set forth in MDUFMA. As a result, FDA reconsidered its prior classification of biopsy forceps as semi-critical devices and correctly concluded that these devices should be considered critical because they "are intended to break the mucous membrane and come in contact with sterile tissue when taking a biopsy."[5]

Other Authoritative Bodies Consider Biopsy Forceps to be Critical Devices

FDA's reclassification of non-electric biopsy forceps is consistent with the approach taken by health care professionals and regulators within FDA itself, who commonly consider biopsy forceps to be critical devices based on the application of the Spaulding criteria. For instance, the American Society for Gastrointestinal Endoscopy (ASGE), one of the leading professional associations of gastroenterology doctors, describes critical use items as "items that enter sterile tissue or vascular spaces, and hence carry significant risk for infection if contaminated. This includes needles, surgical instruments, biopsy forceps, urinary catheters, etc.

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3 Spaulding, E.H., "The Role of Chemical Disinfection in the Prevention of Nonsocomial Infections," P.S. Brachman and T.C. Eickof (ed), Proceedings of International Conference on Nonsocomial Infections, 1970, American Hospital Association, Chicago, 1971:254-274.

4 SGNA, "Infection Control Principles", Gastroenterology Nursing Practice, A Core Curriculum, at 265: Mosby Year Book, Inc. (1993).

5 68 Fed. Reg. at 38072.

Processing for reuse requires *sterilization* for this group of items."[6] By contrast, semi-critical items are those "that contact mucous membranes or non-intact skin. This includes thermometers, endoscopes, anesthesia equipment, and others. Processing for reuse requires *high level disinfection* for these items."[7]

The Society of Gastroenterology Nurses and Associates (SGNA) also considers biopsy forceps to be critical devices "that present a high risk of infection if they are contaminated. These are objects or instruments that come in contact with body tissue below the skin surface or mucous membranes, the vascular system, or other normally sterile areas of the body. Examples of critical items used in the gastroenterology unit would be biopsy forceps and intravenous catheters."[8] In a letter to FDA regarding the reclassification of biopsy forceps, SGNA stated that, "of particular concern to SGNA is the designation of biopsy forceps as Class I exempt. We urge the FDA to rethink this classification of biopsy forceps. This particular device is intended to break the mucosal barrier and thus falls into the Spaulding Classification as a critical device."[9]

Further, FDA itself has consistently considered biopsy forceps to be devices that must be sterilized (rather than disinfected) prior to reuse. In FDA's response to BSC's Citizen's Petition seeking removal of the exemption, FDA acknowledged its "concern that all non-electric biopsy forceps reaching the market be properly sterilized..."[10] Likewise, a CDRH Abstract issued by the Office of Science and Technology, indicates that "If biopsy forceps are to be reused on another patient, they must be adequately cleaned and sterilized."[11] Under the Spaulding classification, devices that must be sterilized rather than disinfected, are those that meet the definition of critical devices. An internal FDA e-mail reiterates the classification as "critical" of those reprocessed single use devices that must be sterilized. The e-mail suggests that biopsy forceps, because of their exposure to high levels of bioburden, should be classified as "ultra-critical" devices. The e-mail states in pertinent part:

> There are criteria already used by the disinfection and sterilization community that could be applied to the reuse of single use devices. They are referred to as the Spaulding criteria and indicate level of

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6 ASGE, "Infection Control During Gastrointestinal Endoscopy," Guidelines for Clinical Application Volume 49, No. 6 (June 1999), *available at* http://www.asge.org/gui/resources/manual/gea_infection.asp.

7 *Id.*

8 SGNA, "Infection Control Principles," Gatroenterology Nursing Practice, A Core Curriculum, Chapter 3, pg. 21 (Mosby Year Book, Inc. 1993). **[confirm]**

9 Letter from Nancy Schlossberg, SGNA President, to Larry Spears, Acting Director, Office of Compliance, CDRH (Apr. 6, 2001) (emphasis added).

10 Letter from Linda Kahn, Deputy Director for Regulations and Policy at CDRH, to Beatrice Biebuyck Regarding BSC's Citizen's Petition of September 20, 2000 (June 28, 2001).

11 CDRH Abstract from OST for the 2000 FDA Science Forum.

> disinfection/sterilization required. Noncritical devices contact only intact skin . . .semi-critical: contact mucous membranes, endoscopes would be included here; critical devices: contact normally sterile sites: all blood contacting devices such as catheters and all implantable devices would be included here as well as pillows, gowns, drapes, gloves that were in the operative field. ***For reuse we would add: ultra-critical devices: devices that have been in contact with body sites with large amounts of bioburden: this would include such devices as biopsy forceps and sigmoidoscopes.*** [12]

Professionals, who have first-hand knowledge of the risk posed by reuse of biopsy forceps, consistently consider them to be "critical" devices under the commonly accepted application of the Spaulding criteria. This provides additional, compelling support for FDA's reclassification of these products as "critical" devices for which the exemption from premarket notification should be terminated.

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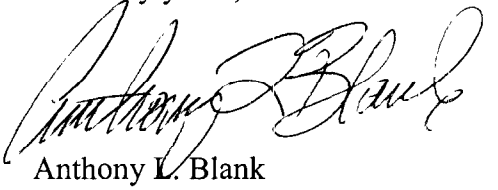
BSC appreciates this opportunity to submit comments on FDA's classification of non-electric biopsy forceps as critical devices and their addition to the list of critical, reprocessed single-use devices for which the exemption from premarket notification requirements will be terminated pursuant to MDUFMA Section 301(b)(2). As discussed herein, BSC strongly supports the inclusion of these devices on the list, and agrees that non-electric biopsy forceps are "critical" devices under the definitions contained in MDUFMA and according to industry practice.

If you have any questions or would like additional information, do not hesitate to call me at 508-650-8798.

Sincerely yours,



Anthony L. Blank
Corporate Regulatory Affairs

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[12] E-mail from Katharine Merritt to Larry G. Kessler and Larry D. Spears, subject line "Reuse Concept" (June 9, 1999) (obtained pursuant to FOIA).