DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

06 JUN 28 2001 10 P1:47

Beatrice M. Biebuyck, Esq.
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: Citizen Petition
Docket Number: 00P-1535
Dated: September 20, 2000
Filed: September 22, 2000
Amended: October 25, 2000

Dear Ms. Biebuyck,

The Food and Drug Administration (FDA) has considered Boston Scientific Corporation's above-referenced citizen petition, as well as the supporting comments filed by the Association of Disposable Device Manufacturers and the Medical Device Manufacturers Association. In your petition, you request that FDA amend Title 21 of the Code of Federal Regulations by revising 21 C.F.R. § 876.1075(b)(2) to limit the exemption from premarket notification requirements for non-electric biopsy forceps to two specified situations: 1) non-electric biopsy forceps which are labeled for single-use and are not reprocessed, and 2) non-electric biopsy forceps which are originally labeled and designed to be reusable.

For the reasons explained below, the agency declines to institute a proceeding to amend the existing regulation and require submission of premarket notifications (510(k)s) for all reprocessed non-electric biopsy forceps.[1] As further explained, FDA recognizes and continues to address concerns about the sterility and reliability of individual biopsy forceps that reach the market. We are conducting investigations and taking appropriate enforcement actions based on the statutory general controls applicable to all non-electric biopsy forceps manufacturers, including both reprocessors and original equipment manufacturers (OEMs).

Under 21 C.F.R. § 876.1075(b)(2), non-electric biopsy forceps intended for use in gastroenterology and urology procedures are class I devices that are exempt from 510(k)

[1] In this response, "reprocessed non-electric biopsy forceps" does not include those devices that are intended for multiple use with interim reprocessing by the end user. As noted, such reusable devices are currently exempt from premarket notification requirements and your petition requests that they remain so.

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notification. In accordance with section 513(d)(2)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*) (FDCA or the Act), FDA exempted these devices after determining that submission of a 510(k) was not necessary to provide reasonable assurance of safety and effectiveness and that devoting agency review resources to such submissions would not advance its public health mission. See 61 FR 1117 (January 16, 1996). Without disturbing FDA's authority under section 513(d)(2)(A), Congress subsequently created an express presumption in law that submission of a 510(k) is not necessary to assure the safety and effectiveness of most class I devices. Thus, under section 510(l), class I devices are not subject to premarket notification requirements unless FDA concludes that they are "intended for a use which is of substantial importance in preventing the impairment of human health," or "present a potential unreasonable risk of illness or injury." See FDCA § 510(l), 21 U.S.C. § 360(l).

Your petition asks the agency to undertake rulemaking that would require the submission of 510(k)s for all members of the reprocessed subset of this generic device type. You contend specifically that reprocessed non-electric biopsy forceps intended for use in gastroenterology/urology (G/U) present a potential unreasonable risk of illness or injury because reprocessing cannot ensure device sterility and because repeated reprocessing may degrade the materials and compromise the performance of the devices. In support of your petition, you submitted studies examining the cleanliness and sterility of biopsy forceps produced by selected reprocessors.[2] Thus, although you seek to require the submission of 510(k) notifications for all reprocessed non-electric G/U biopsy forceps, it is not the reprocessed status itself but a lack of sterility and a propensity for performance failure that you assert present risks requiring a premarket submission.

As explained below, FDA concludes that when produced in compliance with general controls, particularly Quality System requirements, reprocessed biopsy forceps will attain proper sterility and performance and thus do not present a potential unreasonable risk of illness or injury. FDA is increasing its efforts to better enforce those requirements. With such general controls in place, FDA finds that submission of a premarket notification is not necessary to provide reasonable assurance of safety and effectiveness and will not further the agency's public health mission. Consequently, FDA is denying your petition to institute a rulemaking and amend the existing exemption contained in 21 C.F.R. § 876.1075(b)(2) to require 510(k) submissions for the subset of non-electric G/U biopsy forceps produced through reprocessing.[3]

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[2] FDA concentrates primarily on your assertions pertaining to sterility since you did not submit any data supporting your contentions regarding the degradation of materials and performance of reprocessed biopsy forceps, cf. 21 C.F.R. § 860.7, but addresses your performance concerns below as well. For purposes of responding to your petition, FDA assumes that the results reported in the studies you submitted are accurate. FDA has not evaluated the methodology of those studies or otherwise attempted to verify the results.

[3] FDA's prior statements do not require a contrary result. Your petition refers to the assessment of biopsy forceps as "high risk" reusable under a categorization approach found in FDA's draft guidance regarding the prioritization of enforcement against reprocessors. As you are aware, FDA abandoned the risk assessment categorization approach proposed in that draft guidance in light of comments demonstrating that it was arbitrary and unreliable, and that different persons applying the categories would achieve different results. Consequently, FDA no longer endorses the risk evaluations reported in that draft guidance.

In answering your petition, FDA shares your concern that all non-electric biopsy forceps reaching the market be properly sterilized and otherwise perform adequately. Indeed, this is true whether the biopsy forceps are newly manufactured or reprocessed, intended for a single use or multiple uses. But as with any class I device, FDA relies on the general controls under the Act to provide reasonable assurance that the devices meet the appropriate performance standards and, in the case of products labeled to be sterile, this includes assurance that sterility is achieved.

FDA's August 14, 2000, guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" reemphasized that, like other manufacturers, third party reprocessors are subject to all applicable general controls under the statute including registration, listing, medical device reporting, tracking, corrections and removals, quality systems, and labeling. Cf. FDCA section 513(a)(1)(A)(listing general controls to which class I devices may be subject); id., section 513(d)(2)(A) (requiring FDA to expressly state in classification regulation any provisions of section 510, 519, or 520(g) from which a device is exempted).[4] In support of these enforcement efforts, FDA has begun a program to inspect all third-party reprocessors by the end of fiscal year 2001. Furthermore, that guidance announced the agency's intent to phase in, over a one-year period, a more active enforcement of general controls for hospital reprocessors, against whom FDA has not historically pursued active enforcement. All devices -- whether reprocessed or newly manufactured, whether intended for a single use or for multiple uses, and whether exempt from premarket notification under § 876.1075(b)(2) or not -- that are produced without compliance with the Act's general controls are subject to enforcement actions including seizure, recall, injunctions, civil money penalties, and criminal prosecution. We believe these measures will address the underlying concerns identified in your petition.

Of all the general controls, adherence to the Quality System (QS) requirements in particular helps to ensure both process validation and the overall quality of all final production units. QS requirements include validating manufacturing processes (e.g., sterilization), see 21 C.F.R. § 820.75, 61 FR 52631 (Oct. 7, 1996) (preamble to QS regulation, comment 143); instituting quality control over incoming products used to create marketed devices (including whole used devices, in the case of reprocessors), see id. at §§ 820.50, 820.80(b), 820.86; and using procedures to identify, evaluate, and control final product that does not meet specifications. See id. at §§ 820.70; 820.90. These measures help to provide reasonable assurance that G/U biopsy forceps, and all other medical devices legally in commerce, meet the standards for quality and therefore are safe and effective and do not present an unreasonable public health risk.

In addition to FDA's general experience with the effectiveness of QS requirements, the very studies you submitted demonstrate that where QS requirements are met, the resulting reprocessed devices will present no unreasonable risk of harm. Although your studies suggest a lack of consistency in manufacturing by some reprocessors, they also

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[4] FDA did not exempt non-electric G/U biopsy forceps from the Act's general controls. Rather, in proposing their exemption and that of other class I devices in 1995, FDA expressly stated that "FDA's decision to propose 510(k) exemptions for these devices is based, in part, on the fact that compliance with CGMP's [current good manufacturing processes, now enforced through the QS regulation] will help ensure product quality." 60 FR 38904 (July 28, 1995).

demonstrate that it is possible for reprocessors to produce biopsy forceps that are clean and sterile. A reprocessor of an SUD, just like a reprocessor of a device that an OEM markets for multiple use, can provide adequate sterilization.[5] Indeed, your more recent studies of devices reprocessed by the same manufacturers show significant improvement in their ability to produce sterile devices. With proper process validation and monitoring of manufacturing, as required by the QS regulations, all non-electric G/U biopsy forceps coming off the reprocessing line should meet appropriate sterility specifications, as well as other performance specifications that you suggest may be compromised.[6]

FDA is committed to enforcing the QS requirements. As part of FDA's increased oversight for all reprocessed single-use devices, FDA has inspected Vanguard Medical Concepts, Inc., a major third-party reprocessor of non-electric biopsy forceps and the source of the majority of the devices tested in your studies. In response to our inspection, Vanguard has implemented changes in its cleaning and sterilization processes to help ensure conformance with QS requirements.

When FDA inspections or other information reveal failures to satisfy general controls, FDA will respond appropriately, which may include legal actions such as seizure or injunction.

For the foregoing reasons, FDA is denying your petition. If future developments demonstrate that general controls are not sufficient to address risks, FDA will take whatever additional regulatory actions may be appropriate to safeguard the public health.

If you have any questions about this response, please contact Larry Spears, Acting Director, Office of Compliance, at (301) 594-4692.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

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[5] Non-electric G/U biopsy forceps marketed by OEMs for reprocessing and multiple use by the end user are also exempt, but your petition does not request that premarket review be required for these devices.

[6] As you acknowledge, CDRH's Office of Science and Technology determined through its own testing that biopsy forceps could be adequately cleaned. OST did not attempt to sterilize the devices, but it noted that if water remained in the lumen after cleaning, this might impede sterilization with EtO. This indicates that the manufacturing processes employed by reprocessors should ensure that the device lumen is dry prior to the sterilization step. The sterilization instructions provided with non-electric biopsy forceps designed for multiple use, which are exempt from 510(k), similarly instruct users to ensure that the lumen is dry before sterilization. Just as user instructions for multiple-use forceps help to ensure that a proper drying step is included in the user-sterilization process, quality system requirements and inspections will help ensure that reprocessors can produce sterile biopsy forceps by including an adequate drying step if appropriate.