ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS
Providing industry views on single patient use medical devices

December 8, 2000

BY HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
12420 Parklawn Drive, Room 1-23
Rockville, Maryland 20857

Re: Docket No. 00P-1535

Dear Sir or Madam:

The Association of Disposable Device Manufacturers ("ADDM"), respectfully submits these comments in support of Boston Scientific Corporation's ("BSC's") September 20 citizen petition requesting the Commissioner of the Food and Drug Administration ("FDA" or "the Agency") to amend 21 C.F.R. § 876.1075(b)(2) to limit the exemption from premarket notification requirements to (1) non-electric biopsy forceps labeled for single use that are not reprocessed, and (2) non-electric biopsy forceps originally designed and labeled to be reusable.

ADDM is a trade association of medical device manufacturers dedicated to providing information and industry perspectives on issues that affect single use devices. ADDM's goal is to bring about the appropriate regulation of reprocessed single use devices. Such regulation will ensure patient safety, conform to the Federal Food, Drug, and Cosmetic Act ("FDC Act"), demonstrate regulatory fairness, and result in proper allocation of FDA resources. In response to the Agency's request for comments on the regulation of single use device reprocessing, ADDM has previously submitted comments that explored the issue of extending exemptions granted to new medical devices to their reprocessed counterparts.[1] This submission provides comments in support of BSC's petition and general comments in favor of revising FDA's approach to regulating reprocessed Class I or Class II exempt single use devices. In submitting these comments, ADDM hopes to assist FDA in achieving swift resolution of this important patient safety and regulatory fairness issue.

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[1] See e.g., Letter from Josephine Torrente, Esq., President, ADDM, to FDA Dockets Management Branch (FDA Docket No. 00D-0053) (Apr. 10, 2000).

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I. Background

On August 14, 2000, FDA published a notice in the *Federal Register* announcing the availability of a guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (the "Enforcement Guidance").[2] While FDA previously clarified that reprocessing of single use devices is unlawful absent compliance with the premarket submission requirements, the Agency had not enforced these requirements.[3] The Enforcement Guidance finalized the Agency's enforcement policy for the regulation of third-party and hospital reprocessors, and set forth FDA's priorities for enforcing premarket submission requirements for reprocessed single use devices based on the device's classification as established in the Code of Federal Regulations.

On the issue of Class I and II exempt devices, the Enforcement Guidance states that "[a]t a later date, the agency will evaluate, on a case-by-case basis, the need to revoke exemptions from premarket submission requirements for class I and class II exempt products . . . [as is] necessary to ensure that these devices are safe and effective for reuse after reprocessing."[4] In this statement, FDA acknowledges that, once reprocessed, certain exempt Class I and Class II devices are no longer so presumptively safe that agency review should be foregone. Instead, the Agency notes that premarket submissions may be necessary to ensure that the devices are safe and effective.

ADDM agrees with BSC that, in accordance with the Agency's policy announced in the Enforcement Guidance, FDA must immediately revise its regulation that exempts all

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2 FDA, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" (Aug. 14, 2000).

3 See Letter from Larry Spears, Director, Division of Enforcement III, Office of Compliance ("OC"), CDRH, FDA, to Stephen Terman, Esq., Olsson, Frank & Weeda, P.C. (July 9, 1999) ("Third-party reprocessing of devices labeled for single use is unlawful unless those engaged in this practice comply with all regulatory requirements for manufacturers, including premarket notification requirements. FDA has exercised and will continue to exercise regulatory discretion for all premarket notification requirements.").

4 Enforcement Guidance at 10.

non-electric biopsy forceps from premarket notification procedures to exclude reprocessed single use non-electric biopsy forceps. Results of testing submitted in the BSC citizen petition demonstrate that premarket submissions are necessary to ensure that reprocessed single use biopsy forceps are safe and effective for reuse after reprocessing.

More broadly, ADDM maintains that FDA's data-less extension of 510(k) exemptions to any reprocessed single use device inappropriately presumes that the device is safe. The burden of demonstrating safety and effectiveness should reside with the reprocessor, and should be met in a 510(k) or petition for reclassification. Under the new process defined in the Enforcement Guidance, the burden is shifted, leaving interested parties such as BSC to demonstrate the need to revoke exemptions on a case-by-case basis. The burden of affirmatively demonstrating safety should be placed on the party that always has the burden under the FDC Act: the party who wishes to market the device.

II. Non-Electric Biopsy Forceps

Single-use biopsy forceps, whether thermal or non-thermal, are difficult, if not impossible, to thoroughly clean or adequately sterilize for safe reuse in patients without adversely affecting the structural integrity of the device. The very design of non-electric biopsy forceps impedes adequate cleaning and sterilization after use. In addition, the harsh conditions of reprocessing diminish the performance and structural integrity of the device. Reprocessing these devices, with its potential for residual debris, non-sterility, and compromised functionality, presents an increased risk to patients. This risk necessitates 510(k) clearance to ensure that these devices are safe and effective for reuse after reprocessing.

The results of several studies have consistently demonstrated that a significant number of reprocessed single use biopsy forceps contain residual debris and fall below the sterility assurance level established by FDA as appropriate for most medical devices. First, in BSC-sponsored studies performed by independent laboratories, more than 64 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.[5] Second, in studies conducted by FDA's Office of Science and Technology using three types of single use gastrointestinal biopsy forceps, researchers found that, in cleaning the devices with a sequence of bleach, ultrasonic bath with detergent and enzyme, and water rinse, residual water remained in the devices. This inability to adequately dry the device lumen decreases

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[5] See BSC Citizen Petition, at 6-8 (FDA Docket No. 00P-1535) (Sept. 20, 2000).

the effectiveness of sterilization.[6] Thus, even when debris can be removed from these devices, the existence of residual water compromises the ability to effectively sterilize them.

In light of the exemption policy announced in the Enforcement Guidance, and based on the evidence presented by BSC in its citizen petition that reprocessing non-electric biopsy forceps significantly affects the safety of the device, ADDM supports BSC's request that FDA immediately amend its regulation that exempts all non-electric biopsy forceps from premarket notification procedures to exclude reprocessed single use devices.

III. FDA's Extension of Exemptions to Reprocessed Single Use Devices is Inappropriate

A. Failure to Require 510(k)s for Reprocessed Single Use Devices is Inconsistent with FDA Policy Requirements for OEM Devices

The Enforcement Guidance states that FDA intends to subject reprocessed single use devices to premarket submission requirements based on their original device classification as Class I, II, or III devices. Under this classification scheme, FDA exempted certain new Class I and II devices from 510(k) requirements after determining these requirements were not necessary to ensure the safety of the devices. Each device classification was examined to determine whether devices in that classification should be exempt. The added risks of reprocessing were not considered in those examinations. The FDA now intends to extend these premarket exemptions to reprocessed devices despite the Agency's failure to perform a product-by-product review to determine whether valid scientific evidence of safety and effectiveness supports the reclassification. Under the Enforcement Guidance, exemptions from premarket review granted to Class I and II new single use devices are extended in a blanket fashion to reprocessed devices of the same type. Unlike the original exemption process, FDA's new approach has neither a legitimate scientific basis to suggest the appropriateness of this exemption nor individualized determinations.

Multiple use of a device designed for single use only introduces risks that were not factored into the exemption for either single use or reusable devices. The FDA's understanding of those risks is evident in its policy on changing the intended use of a device from single use to reusable. Manufacturers who wish to relabel their single use

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[6] See CDRH, "Reprocessing Single Use Biopsy Forceps for Reuse," Abstract for the 2000 FDA Science Forum from OST.

exempt devices as reusable must submit, and obtain FDA clearance of, a 510(k). This is true even if a similar device, designed to be reusable, is exempt.[7] The 510(k) Guidance makes no distinction between exempt and nonexempt devices. A change from single use to multiple use necessitates a new 510(k) in either situation. This is an appropriate recognition of the inability of the exemption to apply to a reprocessed device designed solely for use on a single patient. The fact that a device designed for multiple use may be sufficiently safe to forego 510(k) clearance cannot be broadened to mean that a device designed to be used once can be safely used in multiple patients.

The Enforcement Guidance conflicts with the 510(k) Guidance and allows single use devices to be reprocessed for use on multiple patients without 510(k) clearance. Under the 510(k) Guidance, a change from an exempt single use to multiple use requires submission of a 510(k) (i.e., the exemption granted to the single use device does not apply to the device when use on multiple patients). Under the Enforcement Guidance, a change from exempt single use to multiple use does not require submission of a 510(k) (i.e., the exemption granted to the single use device does apply to the device when used on multiple patients). The only apparent distinction between these conflicting policies is the identity of the manufacturer. OEMs must submit a 510(k) for such a change while reprocessors are not required to do so for the exact same change.

This inconsistency is the result of a contrived regulatory scheme designed to lower the traditional medical device requirements to a level that can be met by reprocessors of single use devices. The FDA has consistently evidenced its intent to utilize the Quality Systems regulation, in isolation of premarket requirements, to regulate reprocessing. In striving to achieve this end, FDA has attempted the wholesale exemption of hundreds of reprocessed single use devices and created a major inequity in its regulation of OEMs and reprocessors.

B. Case-by-Case Analysis of Exemptions Presumes Safety of Reprocessed Single Use Devices and Inappropriately Shifts the Burden of Proof

Under its new policy, FDA presumes that an exemption granted to a new device is automatically extended to a reprocessed single use device of the same type. To rebut this presumption, FDA says it must determine, on a case-by-case basis, that additional risks may exist due to reprocessing. Under the Enforcement Guidance, the data on which FDA

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[7] See Guidance: Deciding When to Submit a 510(k) for a Change to an Existing Device, ODE, CDRH, FDA, at 9 (Jan. 10, 1997) (the "510(k) Guidance).

will base that determination must come from FDA itself, or from interested third parties, such as OEMs and consumer groups. Such a policy is inconsistent with FDA precedent, fails to protect patients, and creates regulatory inequity. Since enactment of the Medical Device Amendments of 1976, FDA has consistently maintained that devices can only be reclassified or exempted based on publicly available valid scientific evidence of safety and effectiveness to support that action.[8] That evidence must demonstrate that the proposed exemption will provide a reasonable assurance of safety and effectiveness. No such data has been made publicly available for any reprocessed single use device.

Instead of placing the burden on a reprocessor to prove that the device it manufactures is sufficiently safe to warrant an exemption, FDA intends to allow reprocessed single use devices to be used on patients until either FDA expends its scarce resources to study the issue, or other interested parties conduct studies to demonstrate that the devices are unsafe. While BSC has met this standard, it is not the responsibility of an OEM to prove the lack of safety and effectiveness of another manufacturer's reprocessed device. As noted by the court in Contact Lens Mfrs. Ass'n v. Food and Drug Administration, "The FDA has consistently maintained that *proponents of reclassification assume the burden* of demonstrating – through 'publicly available, valid scientific evidence'- that the device's present classification is inappropriate and that the proposed classification will provide reasonable assurance of the device's safety and effectiveness." (Emphasis added).[9]

Conclusion

Based on testing results from both BSC and FDA, it is clear that reprocessed single use non-electric biopsy forceps without 510(k) clearance are not safe or effective for reuse. Thus, ADDM believes that FDA must immediately revise its regulation that exempts all non-electric biopsy forceps from premarket notification procedures to exclude reprocessed single use non-electric biopsy forceps. More globally, FDA's broad extension of exemptions to hundreds of reprocessed single use devices is inappropriate insofar as the

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8 21 C.F.R. § 860.7.

9 See Contact Lens Mfrs. Ass'n v. Food and Drug Administration, 766 F.2d 592, 599 (D.C. Cir. 1985); see also United States v. An Article of Device . . . "Toftness Radiation Detector", 731 F.2d 1253, 1260 (7th Cir. 1984) (stating the general principle that "a party claiming entitlement to a statutory exemption bears the burden of proving the entitlement").

Agency presumes safety rather than requiring reprocessors to meet the burden for obtaining an exemption or filing a 510(k). ADDM believes that this presumption is inconsistent with the FDC Act, FDA's regulations, sound policy, and patient safety.

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ADDM appreciates the opportunity to submit these comments and looks forward to FDA action on this issue.

Respectfully submitted,

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President

JMT/dmh

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