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BARD

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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:

C. R. Bard respectfully submits these comments in support of the September 20, 2000, Citizen's Petition submitted by Boston Scientific Corporation to limit the exemption under 21 C. F.R. (para) 876.1075 (b) (2) to (1) non-electric biopsy forceps for single use that are not reprocessed, and (2) non-electric biopsy forceps originally designed and labeled to be reusable. As a manufacturer of devices that are within this classification, Bard shares with Boston Scientific the concerns raised in the petition regarding the ability of reprocessors to adequately clean and re-sterilize non-electric biopsy forceps intended for single use and assure that they remain safe and effective.

Introduction

Non-electric biopsy forceps are intended to breach the mucous membrane barrier to achieve their intended use. Their ability to cut and cleanly deliver an adequate tissue sample for evaluation, as well as the requirement that no infectious agents or deleterious material be introduced into the site during this process are the foci of the concerns raised regarding reprocessing. These same issues are in fact the foci of the work done by Original Device Manufacturers when non-electric biopsy forceps intended for reuse are designed and tested. It is incumbent upon the FDA and reprocessors to assure users that only substantially equivalent product will be introduced into the market. In the case of single use products, the materials and basic design of the devices have been chosen specifically to provide disposable devices and there is no intent to support their ability to be reprocessed. Due to the basic design intent of the "raw materials" as noted above, their appropriateness for market entry can be achieved only by an unbiased review of the data upon which claims of equivalence, equivalence for safety and effectiveness, are made. FDA must provide this review and therefore should limit the exemption from 510(k) for biopsy forceps to devices marketed according to the intent of the original design and materials, single use disposable or designed, manufactured and originally labeled for re-use.

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Exemption From 510(k)

Exemption from pre-market review, a classification determination, has in the past been based on a conclusion that such review is not necessary to ensure the safety and effectiveness of a given device type, or a subset of devices within a type. Such a conclusion was reached only after evaluation of data supporting a history of safe and effective use. Lacking such a history for reprocessed single use devices in a setting where there is risk to the patient from a non-sterile or compromised product and still allowing the exemption, does not appear to be in keeping with the way in which FDA has performed classification determinations in the past.

In those cases where the manufacturer of a single use product, after obtaining experience in cleaning and re-sterilization of the device and developing supporting data regarding materials and manufacturing, chooses to change the labeling and intended use of their own device to claim re-use, a 510(k) is required to support the change in claim. The device is not considered to remain in an exempt category until it has been demonstrated to fit the category, that is the device will remain safe and effective when used in this new way. It does not appear that the exemption of reprocessed single use biopsy forceps submitted by someone other than the original manufacturer is in keeping with this policy and practice under 510(k).

Although under FDAMA, Class I devices were to be considered for exemption from pre-market notification, discretion was given to FDA to consider whether the risk that a Class I exempt device might pose was reasonable. It is our conclusion and that of others, that the risk from reprocessed single-use biopsy forceps is both unreasonable and avoidable. Data from both ECRI and the FDA itself demonstrate that there is significant risk for reprocessed single-use forceps. Data demonstrated that when a biopsy forceps is designed for single-use it cannot be adequately cleaned and sterilized and may be damaged in such a way that it will no longer perform safely or effectively. These data are exactly the sort of information that FDA was intended to consider in the exemption of Class I devices. It appears that this has not taken place.

Conclusion

Given that exemptions from 510(k) should be based on a history of safe and effective use, that there is data to support a conclusion that reprocessed biopsy forceps labeled for and intended by the original manufacturer to be single-use pose unreasonable and avoidable risk, and that FDA has both the discretion to limit those products within a given category that may be exempted from pre-market notification and has noted its intent to consider the appropriateness of continued exemption for reprocessed single-use devices, 21 C.F.R. .....should be amended as requested in the petition by BSC.

Respectfully submitted,

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for Susan Alpert

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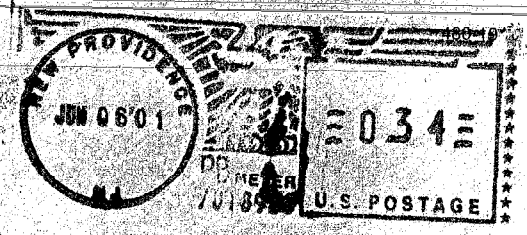

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