

# Boston Scientific

March 14, 2002

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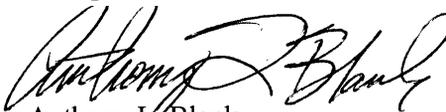
Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Ref. Docket No. 01D-05 14

To Whom It May Concern:

In response to the above referenced Federal Register Notice published on December 20, 2001, Boston Scientific Corporation is submitting, in duplicate, recommendations on the content of a guidance document to be drafted on the labeling of reprocessed single use devices (SUDS) with respect to the name of the original equipment manufacture (OEM) and the remanufacturer (i.e., reprocessor). If you require any clarification to recommendations described herein, please do not hesitate to contact me at (508) 650-8798.

Sincerely,-



Anthony L. Blank  
Manager, Corporate Regulatory Affairs

Enclosure

01D-0514

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Labeling Element	Recommendation	Rationale/Foundation
Device Label	<p>In the event that the label of the device bears any identification of the original equipment manufacturer (OEM), then the label of the device should additionally bear appropriate language which:</p> <ol style="list-style-type: none"> <li>1. Unambiguously notifies the user that the device has been remanufactured by the <i>Reprocessor</i> from a device originally manufactured by the OEM. The notice should be displayed using text no smaller than the largest text used to identify the OEM on the device label. Recommended language is:   <i>"The [medical device name] is a medical device that has been remanufactured by [Reprocessor] from a device originally manufactured by [OEM]."</i></li> <li>2. Unambiguously informs the user that all complaints and reports of adverse effects are to be reported to the <i>Reprocessor</i>. Recommended language is:   <i>'Report all complaints and adverse effects associated with the use of this remanufactured device to [Reprocessor Name, Address, Telephone Number].'</i></li> </ol>	<p>In order to comply with the reporting requirements described in §803.32, user facilities must include the Manufacturer name and address in FDA Form 3500A (per 803.32(c)(3)). We believe that failure to display the name and address of the Reprocessor on any device label that bears identification of the OEM (either directly or indirectly through the use of trademarked names or symbols) is likely to lead to misidentification of the OEM (<i>rather than the Reprocessor</i>) as the manufacturer in user facility reports. We believe that such errors would compromise the intended function of the reporting program (i.e., monitoring the marketplace for risks to consumers).</p> <p>In addition, we believe that identification on any device label of the OEM without concurrent identification of the <i>Reprocessor</i> is likely to lead to reimbursement errors (e.g., reprocessed devices submitted for reimbursement as a new - rather than reprocessed - device).</p>
All	<p>A <i>Reprocessor</i> should not be allowed to either state, imply or infer that a remanufactured device meets the original design specifications established by the OEM. An example of a statement we believe should be prohibited is... <i>"Meets the original manufacturer's own specifications"</i>.</p>	<p>While the <i>Reprocessor</i> may have obtained clearance or approval to market a remanufactured device on the basis of the ability of the remanufactured device to meet certain performance specifications - the <i>Reprocessor</i> would not typically have access to the complete design specifications established by the OEM for the original device. Consequently, we believe that any assertion made by a <i>Reprocessor</i> that the remanufactured device meets (or exceeds) the original design specifications would be a misleading statement and would thus render the device <u>misbranded</u> (per §801.6).</p>

Labeling Element	Recommendation	Rationale/Foundation
Warnings	<p>Users of reprocessed medical devices should be aware of the possible increased risk of receiving a device that is the subject of a recall or field corrective action. We recommend the following wording:</p> <p><b>Warning</b>     <i>This device is a remanufactured device. The original manufacturer of this device has no record of its sale to you. Therefore, it is unlikely that either you or the Reprocessor from whom this device was purchased will receive notification of any recalls or-field corrective actions from the original manufacturer. Consequently, there is an increased risk of serious patient injury or death associated with the use of a device that was intended to have been either repaired or removed from distribution at the request of the original manufacturer.</i></p>	<p>The OEM will have access only to the purchasing and delivery records associated with the original distribution of the original device. Once the initial purchaser has submitted the device to a <i>Reprocessor</i> for remanufacture, the OEM will have lost the ability to locate the remanufactured device. Consequently, patients who receive treatment or therapy with a reprocessed medical device that is the subject of an OEM-initiated correction or removal intended to reduce a risk to health posed by the device will be subject to an increased risk of serious injury (or even death).</p> <p>We believe that failing to provide the user with adequate notification of this risk is a failure to provide adequate information for use.</p>
Labeling (other than Device Labels)	<p>Labeling for remanufactured medical devices (other than labels affixed to the device) should not provide identification (either explicit or implicit) of the OEM. "Labeling" is as defined in Section 201(m) of the Federal Food Drug and Cosmetic Act.</p>	<p>Identification of the OEM in labeling of remanufactured devices (such as brochures and other promotional material) cannot reasonably serve any material purpose other than implicit promotion of the effectiveness or safety of the device on the basis of the identity of the original manufacturer.</p> <p>In that the device is remanufactured to the <i>Reprocessor's</i> specifications (<u>not</u> the OEM's), it is our opinion that such an implication is misleading and would thus render a device <u>misbranded</u> (per §80 1.6).</p>

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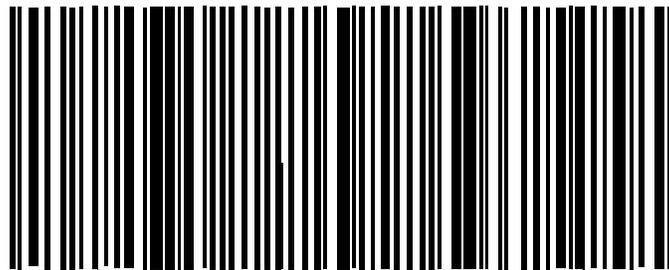
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