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Healthcare

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March 18, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, rm.1061  
Rockville, MD 20852

**Re: Docket No. 01D-0514**  
Medical Devices; Guidance on Labeling of Reprocessed Single Use Devices; Request  
for Comments and Information

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Dear Sir or Madam,

Tyco Healthcare hereby submits the following comments in response to FDA's notice (12/20/2001) in the Federal Register requesting comments and information on the contents of the proposed 'Guidance on Labeling of Reprocessed Single Use Devices'. In preface, Tyco completely endorses the comments and objections made in the citizen petitions filed on March 22 and August 3, 2001 by the Association of Disposable Device Manufacturers (ADDM) regarding the contraindicated reprocessing of single use devices.

Our comments address in particular the misleading representation that unavoidably results when a reprocessed device bears, as imprinted on the original product, the OEM's name and trademarks, and omits the reprocessor's name. This outcome is in direct conflict with 21 CFR § 801.6, which states, "Among representations in the labeling of a device which render such device misbranded is a false or misleading representation with respect to another device..." In its response to ADDM's petition (Docket #01P-0148), the FDA similarly noted that it "agrees that certain representations with respect to an OEM on a reprocessed device may be misleading." Of course, the presence of OEM trademarks and other identifying information relating to the OEM, without any information identifying the device as reprocessed or the reprocessor, would be misleading. FDA's letter back to ADDM further recognized the importance of reprocessor's identification, and stated, "FDA believes that when a reprocessed product's labeling makes representation that suggest the OEM should be notified of product problems, additional information that provides the correct identity of the reprocessor as the remanufacturer who is responsible for adverse event reporting, recalls, or other corrective actions, is 'material' information within the meaning of section 201(n) of the Act<sup>1</sup> because such information is necessary to enable FDA's postmarket reporting procedures under section 519 of the Act to function effectively."

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<sup>1</sup> The Federal Food, Drug, and Cosmetic Act (the Act), as amended by the Safe Medical Devices Act of 1990, the Medical Device Amendments of 1992, and the Food and Drug Modernization Act of 1997.

Identification of a reprocessor solely on packaging that accompanies a device will be ineffective for purposes of enabling adverse event reporting. Such packaging is typically discarded prior to use of the device and the occurrence of any related adverse event. The result may also be an incomplete investigation of the product complaint, as there will be no indication that the adverse event could have resulted from failed reesterilization, materials weakened, blades dulled or other adverse consequences of repeated or failed reprocessing. Consequently, in order to achieve effective and reliable adverse event reporting, it is crucial that a reprocessed designation and identification of the reprocessor appear directly on all reprocessed devices.

In addition to being necessary to avoid false or misleading representations, and enable postmarket reporting procedures, identification of the device as reprocessed is also material to an informed exercise by the physician of his or her clinical judgment to use the device for a particular procedure or patient. However, if this information appears only on package labels, it will typically be discarded with the packaging prior to placement of the device in the sterile field and the physician's inspection and use of the device. The omission of such information on the device will necessarily mislead the physician to believe the device is in its original new condition in every respect. Consequently, this information will not be reliably communicated to the physician unless, in addition to any package labels, it appears on the device, itself. For this reason, it is essential that the FDA Guidance document, direct that the reprocessor, in addition to placing information on package labels, also place a "reprocessed" designation and the name of the reprocessor directly on the device. Furthermore, in order to avoid confusion or oversight, the reprocessed designation and identification of the reprocessor should be more prominent than, and in close proximity to, any OEM trademark or other identification that may also appear on the device.

As demonstrated above, the only means to avoid misleading or false representations, enable reliable and effective adverse reporting, and provide physicians with information material and necessary to the exercise of their clinical judgement, is to require that reprocessors permanently place, directly on reprocessed devices, a legible and prominent label that identifies the device as reprocessed and identifies the reprocessor. Therefore, Tyco Healthcare urges the FDA to include these requirements in its proposed Guidance on Labeling of Reprocessed Single Use Devices.

Thank you for this opportunity to provide our comments on the draft guidance.

Sincerely,



Lawrence T. Gibbons  
Vice President  
Quality Assurance and Regulatory Affairs

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