

ASSOCIATION OF DISPOSABLE DEVICE MANUFACTURERS

Providing industry views on single patient use medical devices

June 5, 2002

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BY HAND DELIVERY

Docket Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

**Re: Docket No. 02D-0039; Draft Guidance for Industry and FDA on
Premarket Notification Submissions for Medical Sterilization Packaging
Systems in Health Care Facilities**

Dear Sir or Madam:

The Association of Disposable Device Manufacturers ("ADDM") respectfully submits these comments in response to the Food and Drug Administration's ("FDA" or "the Agency") March 7, 2002 Federal Register notice, at 67 Fed. Reg. 10,418, requesting comments on the Agency's draft guidance document, titled "Premarket Notification [510(k)] Submissions for Medical Sterilization Packaging Systems in Health Care Facilities" ("Packaging Premarket Guidance"). This guidance document sets forth the data requirements for obtaining a 510(k) for medical device sterilization packaging, including packaging that will be reprocessed and used again.

ADDM is a trade association of medical device manufacturers whose mission is to provide information and industry perspectives on issues concerning single use medical devices. Since its formation more than three years ago, ADDM has sought appropriate FDA regulation of entities that reprocess single use devices contrary to their labeling and approval. As noted in FDA's August 14, 2000 guidance document, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," such regulation includes enforcement of all aspects of the Quality System Regulation and enforcement of the premarket submission requirements of the Federal Food, Drug, and Cosmetic Act. ADDM has commented extensively on FDA's evolving policy for regulating reprocessors of single use devices. With regard to FDA's premarket submission requirements for 510(k)s for reprocessed single use devices, ADDM has repeatedly noted (and objected to) FDA's failure to require data demonstrating the safety of these devices for reuse. A full copy of ADDM's comments to FDA's June 2001 draft guidance document, "Premarket Guidance: Reprocessing and Reuse of Single-Use Devices" ("Reprocessed Device Premarket Guidance") is at Attachment A.

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A comparison of the Reprocessed Device Premarket Guidance to the Packaging Premarket Guidance affirms FDA's departure from true premarket review for 510(k)s submitted for reprocessed single use devices. Most importantly, the Packaging Premarket Guidance identifies critical information that must be included in a 510(k) for device packaging intended to be reprocessed, such as, for example, the limits of reuse, the procedures for reprocessing device packaging (including the cleaning parameters, cleaning action, cleaning detergent, cleaning endpoint, and tracking), data to demonstrate that the packaging maintains its original specifications after reprocessing, and validated instructions for reprocessing the device. In contrast, the Reprocessed Device Premarket Guidance requires no such information in 510(k)s for reprocessed single use devices.

The result is an untenable dichotomy in FDA policy in which the device packaging is subject to more stringent data submission requirements and FDA review than the device in the packaging.

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ADDM appreciates the opportunity to submit these comments to FDA and looks forward to an Agency policy that articulates the premarket submission requirements for reprocessed single use devices in a manner consistent with other policies published by the Agency.

Respectfully submitted,



Josephine M. Torrente

KRK/dag

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cc: David W. Feigal, Jr., M.D., M.P.H.
Director, CDRH

Bernard F. Statland, M.D., Ph.D.
Director, Office of Device Evaluation, CDRH

Docket No. 01D-0232

Docket No. 01P-0340