



Food and Drug Administration
Rockville MD 20857

DEC 29 2001

Ms. Josephine M. Torrente
Association of Disposable Device Manufacturers
PO Box 344
1429 G Street, N.W.
Washington, DC 20005

Re: Citizen Petition 01P-0340

Dear Ms. Torrente,

This is in response to your petition dated August 3, 2001 and filed by the Food and Drug Administration on August 7, 2001. In your petition, you request that FDA:

- 1) Issue an announcement that reprocessed single use devices are "reuseable devices" and cannot be labeled, cleared, or approved for single use only.
- 2) Refuse to approve PMAs or clear 510(k)s for reprocessed single use devices that are labeled "single use only" or for which adequate data for multiple use are not provided.

In support of your petition, you make the following arguments:

- 1) Reprocessed single use devices are intended for multiple use.
- 2) Reprocessed single use devices labeled "Single Use Only" are misbranded.
- 3) FDA's policy is arbitrary and capricious and a violation of the Administrative Procedure Act.
 - a) FDA's multiple single use policy is a departure from Agency precedent.
 - b) Implementation of FDA's policy will result in disparate treatment of similarly situated parties.

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c) FDA's policy is illogical and results in arbitrary outcomes.

Certain provisions of the Medical Device User Fee and Modernization Act of 2002 (Public Law 107-250) (MDUFMA) have rendered your petition moot. FDA discussed this issue with you some time ago but you did not agree and did not withdraw your petition. In the interim, CDRH directed most of its resources to implementation of MDUFMA, including those provisions related to reprocessing. For that reason, our answer to your petition was not able to assume a high priority and we apologize for the extreme delay in sending out a formal response. Accordingly, for the reasons discussed below, FDA is denying your petition.

Section 302(d) of MDUFMA added section 201(11) to the Federal Food Drug and Cosmetic Act (the act) (21 U.S.C. 321(11)). This section defines the terms "single use device" and "reprocessed." Section 201(11)(1) defines "single use device" as, "a device that is intended for one use, or on a single patient during a single procedure." Section 201(11)(2)(A) defines "reprocessed" with respect to a single-use device as an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition."

Section 302(a) of MDUFMA added a new section 502(v) to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(v)). This new section provides that:

[A device is deemed misbranded] (v) If it is a reprocessed single use device, unless all labeling of the device prominently and conspicuously bears the statement "Reprocessed device for single use. Reprocessed by _____." The name of the manufacturer of the reprocessed device shall be placed in the space identifying the person responsible for reprocessing.

The first action you request - that FDA announce that reprocessed single-use devices may not be labeled, cleared, or approved for "single use only" - is not consistent with the requirements of section 502(v). Section 502(v) not only permits but requires that reprocessed single-use devices be labeled "reprocessed for single use."

Therefore, FDA is denying the first action requested in your petition.

The second action you request is also inconsistent with section 502(v) to the extent that it requests that FDA refuse to approve or clear reprocessed single-use devices that are labeled "single use only." Section 502(v) requires that reprocessed single-use devices be labeled "reprocessed for single use." In the alternative, you ask in the second requested action that FDA refuse to approve or clear reprocessed single-use devices "for which adequate data for multiple use are not provided." MDUFMA has addressed this portion of your request.

Section 302(b) of MDUFMA added section 510(o) to the act (21 U.S.C. 360(o)). This section requires that FDA identify reprocessed single-use devices for which manufacturers must submit validation data "regarding cleaning and sterilization, and functional performance demonstrating that the single-use device will remain substantially equivalent to its predicate device after the maximum number of times the device is reprocessed as intended by the person submitting the premarket notification." Similarly, section 302(c) of MDUFMA added to the act new section 515(c)(2), which requires that PMAs for class III reprocessed single-use devices include the same validation data identified in section 510(o). Under these provisions, FDA reviews validation data for all class III, PMA-approved, reprocessed single-use devices and for those 510(k)-cleared reprocessed single-use devices for which FDA determines such data are necessary.

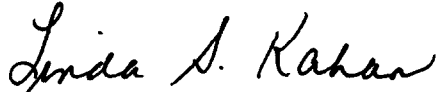
Your second requested action conflicts with section 510(o) because it requests that FDA require validation data for

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all reprocessed single-use devices. Section 510(o) requires validation data only for those devices "for which reports under [subsection (k)] must, in order to ensure that the device is substantially equivalent to a predicate device, include validation data." Consistent with section 510(o), FDA has identified those devices subject to section 510(k) requirements that need validation data. Because of the conflict between your second requested action and sections 502(v) and 510(o) of the act, FDA is denying this request

If you have any questions about this response, please contact Heather S. Rosecrans at 301-594-1190.

Sincerely yours,



Linda S. Kahan
Deputy Director
Center for Devices
and Radiological Health