1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

Pamela G. Bailey
President

Direct: 202 434 7200
pbailey@AdvaMed.org

AdvaMed
Advanced Medical Technology Association

June 5, 2001

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

Re: Comments to Citizen Petition Regarding the Misbranding of Reprocessed Single Use Devices: Docket No. 01P-0148.

Dear Sir or Madam:

The Advanced Medical Technology Association (AdvaMed) respectfully submits these comments on a citizen petition regarding the misbranding of reprocessed single use medical devices submitted by the Association of Disposable Device Manufacturers. AdvaMed represents more than 800 innovators and manufacturers of medical devices, diagnostic products and medical information systems. Our members produce nearly 90 percent of the $68 billion health care technology products consumed annually in the United States, and nearly 50 percent of $159 billion purchased around the world annually.

The referenced petition argues that display of Original Equipment Manufacturer (OEM) trademarks on reprocessed single use devices, and references to the OEM in the reprocessed device's labeling, render the devices misbranded under the Federal Food, Drug, and Cosmetic Act (FDC Act). The petition requests that FDA (1) issue an announcement recognizing such devices as misbranded, (2) enforce the misbranding provisions of the FDC Act against entities who conduct such misbranding activity, and (3) refuse to approve or clear any reprocessed single use devices absent assurance by the reprocessor that the device will not be misbranded in this way.

AdvaMed supports the referenced petition and the actions it requests. Proper regulation of single use device reprocessing involves ensuring that OEM names and trademarks do not appear on reprocessed devices so that physicians are aware that the device is not backed by the OEM, and adverse events are attributed to the reprocessor, not the OEM. This issue of the OEM trademark is especially troubling in light of FDA's recently announced view that reprocessed devices are "new" medical devices whose manufacturer is the reprocessor.

01P-0148

C3

Trademarks are vitally important to AdvaMed's members, and the medical device industry as a whole. As such, AdvaMed requests that FDA grant the actions requested in the referenced citizen petition, and recommends that FDA implement the proposed initiatives in as expeditious a manner as possible.

AdvaMed appreciates the opportunity to provide its comments on this matter.

Respectfully submitted,

Pamela G. Bailey