

# MAQUET

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March 12, 1998

In reply to: Federal Register, Dec. 23, 1997

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Dockets Management Branch (HFA-305)  
Food and Drug Administration  
12420 Parklawn Drive, Rm. 1-23  
Rockville, MD 20857

To Whom It May Concern,

SUBJECT: PROPOSED RULES - DOCKET # 97N-0477

I am writing today on behalf of MAQUET Corporation to convey our thoughts on the proposed regulations regarding refurbishers, rebuilders, reconditioners, servicers, and "as is" remarketers of medical devices. MAQUET Corporation is an importer and MDR reporting site for our home office in Rastatt Germany (MAQUET AG). We import some of the world's finest operating room tables and accessories. For the last ten years, our home office has used distributors of other medical devices to promote our products (Siemens, Heraeus, and Laserscope). In January of this year, the decision was made to establish a presence in the United States and represent our interest directly.

We have discovered that the use of distributors has actually provided "remaufacturers", "refurbishers", and "service" providers segue to position themselves between the device manufacturer and the original owner/user. Clearly, there are many of these entities in the marketplace wearing the moniker of "remanufacturer", or "refurbisher" solely to access a loophole in the current Federal regulations with respect to medical devices. For obvious reasons, we are extremely anxious for the FDA to institute regulations to govern the activities of the above mentioned entities.

In section IV of the proposed definitions of remarketing activities, the FDA has requested comments as they relate to ownership of devices. Our contention is with the verbiage used in each definition, "do not significantly change a finished device's performance or safety specifications, or intended use." How do they know what our specifications are, and if they are changed or not? The statement suggests that these entities have access to our every specification and test protocol. With respect to our finished goods, this information is considered proprietary and it is not given out to just anyone with a set of tools and a lead on a used table. We have spent many hours and many dollars constructing our Quality System and training MAQUET agents on the requisite skills necessary for maintaining quality throughout the life of the product. The definition should reflect the truth in that these entities are actually using their own perception of manufacturer specification, quality and performance.

97N-0477

MAQUET Corporation

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In addition, the FDA has requested information on the following points;

1. *Has FDA appropriately defined the terms, refurbisher, as is remarketers, and servicers? If not, what changes to these definitions should be made? See previous paragraph.*
2. *What evidence exists regarding actual problems with the safety and/or performance of remarketed devices that are the result of remarketing? Specific examples should be submitted.* We referred to the Internet and the CDRH's Medical Device database to help provide you with specific examples (see addendum A). Instead of asking us for specific examples, we would ask the FDA how many injuries or deaths must occur before the U.S. Government takes appropriate action in regulating entities who are involved with the sale of used medical devices?
3. *What is the appropriate level of regulatory controls that should be applied to persons who remarket devices? Persons who remarket devices should be held to the same regulatory controls that are applied to the original manufacturer. As I mentioned before, it takes a great deal of preparation, manpower, and money to adhere to the directives given to original device manufacturers by the FDA. If there are requirements created for us to follow in producing safe and efficacious medical devices, the same or even greater requirements must be placed on those who remarket the same devices. If it costs them as much as it cost us to ensure quality and safety then you can bet these entities would not even be involved in this activity, and we would not be participating in this exercise. You would cut too deeply into their profit margins for them to stay afloat.*
4. *Should refurbishers, as is remarketers, and servicers be subject to the same or different regulatory requirements? See our response to the previous question. Any regulations must be made to be mandatory, none of what is being proposed should be voluntary.*

The U.S. Government and medical device manufactures share a common concern relating to the unregulated activities of the above mentioned entities, and that is safety of the patient. Among considerations for required activity for refurbishers, rebuilders, reconditioners and "as is" remarketers of medical devices should be the required removal of the original device manufacture's labeling (data plates, decals, etc.) and replacing them with;

1. The name and model identifiers of the refurbisher, builder, reconditioner or "as is" remarketer.

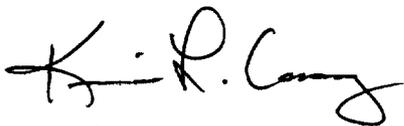
OR

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2. Labeling clearly identifying the device as "remanufactured, rebuilt, reconditioned, or 2<sup>nd</sup> hand."

At the very least, this would provide patients with information with which to make a decision on whether they want to entrust their lives to 2<sup>nd</sup> hand medical devices, or not. Take that decision away from cost-cutting facilities that truly consider the bottom-line a higher priority than patient safety.

Sincerely,

A handwritten signature in black ink, appearing to read "K. L. Casey". The signature is fluid and cursive, with a large initial "K" and a long, sweeping underline.

Kevin L. Casey  
Director of Technical Service  
MAQUET Corporation

cc: Mr. Cory Alcala, President-MAQUET Corp.  
Mr. Reinhard Pfeuffer, Chief Eng.-MAQUET AG  
Mr. Bill Fugate, Mgr. Tech. Svcs.-Berchtold

**Center for Devices and Radiological Health**

## Medical Device Reporting Search

This search mechanism allows you to search the CDRH's Device Experience Network (DEN) database, information on medical devices which may have malfunctioned or caused a death or serious injury during the years 1992 through 1996.

You may search for any text contained in the records. You may also use words such as **AND** and **OR** to join words together in your search term (Boolean logic). After entering search terms in the space below, click on the Search button (do not press the *Enter* key). Use the Search Help to narrow your topic if you receive too many records.

**Enter Search Terms:**

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0.80	<a href="#">M199263</a>	BEAR CUB INFANT VENTILATOR
0.78	<a href="#">M877542</a>	CALIBRATED VAPORIZER
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0.78	<a href="#">M841933</a>	AMSCO 2080MIA SURGICAL TABLE
0.78	<a href="#">M807812</a>	MEVATRON
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0.78	<a href="#">M367213</a>	LIFEPAK DEFIBRILLATOR/MONITOR
0.78	<a href="#">M364122</a>	MONAGHAN 225 SIMV MRI VOLUME VENTILATOR

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