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March 15, 2002

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

Dear Sirs,

The following comments are a response from ClearMedical, a third party reprocessor (TPR) of medical devices, to the posted FDA request for comment on the request from the Association of Disposable Device Manufacturers (ADDM) to require TPRs to remove OEM's trademark from any reprocessed devices and that the FDA enforce this policy via premarket reviews, etc.

The removal of a device OEM trademark is not in our opinion a requirement that serves to enhance the safety or functionality of a reprocessed device. In point of fact, it may contribute to a failure to completely identify a device for the purposes of inventory management, distribution within the healthcare setting, and if a product alert is issued relative to its safe use in the hospital setting, its complete identification.

This is an unusual request given it applies to no other device category except reprocessible devices done by TRP. Hospitals are not required to remove labels on devices they reprocess and we feel there is no compelling reason to begin this process where hospitals choose to contract with a TPR.

It is also worth noting that the TPR in most cases does not own the device that is being reprocessed. The contracting healthcare institution owns the product and "defacing" the device would seem to be the hospital's requirement/choice, not the TPR. While the hospital could be compelled to "deface" the product as a prerequisite to entering into a TPR contact, again, what safety or functionality is served by this action?

Manufacturers around the world sell their products to customers and the customer is not required or compelled to alter the product to have it restored (cleaned/repairs, etc) for reuse. There is no evidence to support this practice if the case of reprocessing (cleaning/testing/disinfecting and repackaging) of a medical device.

OIP-0148

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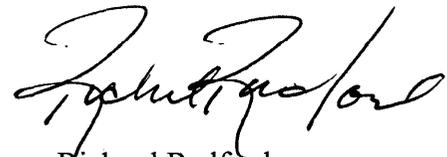
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Our view is that this is a tactic on the part of the OEM to create barriers to the reprocessing of their devices. If adopted, it would add cost and reduced throughput to the reprocessing service, whether it is performed by the hospital or a TPR. We at ClearMedical are committed to the safe reuse of a medical device and at costs to our hospital customers that will contribute as a solution to the financial crisis they all face. In short, we oppose this petition on the part of ADDM and recommend the FDA reject any efforts on the part of OEM which may act as a barrier to reprocessing of their devices unless it will address in a positive manner the issues of safety and functionality of the specific device in question.

Sincerely,


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Chief Scientific Officer
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