

April 30, 1998

7135 '98 MAY -5 A9:44

Mr. Casper E. Uldriks
CDRH
2098 Gaither road
Rockville, Md. 20857

Via fax

Dear Mr. Uldriks:

In response to the Federal Register notice of March 25, 1998 Volume 63, Number 571
Page 14390-14391, I submit the following comments.

To provide for as safe an environment for the Refurbisher, Rebuilders, Reconditioners,
Servicers and "As Is" Remarketers of Medical Devices and of course and most important
the patients needing these Devices, I suggest the following:

1. In order to comply with the guidelines, as set forth in the proposed Revision, it is apparent that access to much needed manufacturing materials will be required. I suggest reducing the Trade Secret Protection granted in 21CFR 20.61(d) from the current 10 year period to a more realistic 3 year time limit. Additional Trade Secret protections, if any, would be reduced to the same time limit.
2. Until the FDA is willing to vigorously enforce the current regulations, in regards to Manufacturers obligations, no new regulation will work and the penalties to patients and small companies will be many. The FDA cannot allow what is currently going on to continue. I suggest that the current system of enforcement be given nothing less than top priority until the Manufacturers "**get the picture**".

I strongly support the need to assure a safe environment for Patients and Employees assembling and servicing Medical Devices. However, the burden of the obligation still must fall on the Medical Device Manufacturer, as it has been for 30 years, to assure safety throughout the life of the medical device. This I believe was the intent of Congress and the FDA some 30 Years ago when this all started.

If you have any questions, please feel free to call me at (724) 934-3932.

97N-0477

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Sincerely,

A handwritten signature in black ink, consisting of a stylized 'T' followed by a large, loopy 'Q' and 'I'.

Thomas J. Quinn

Cc:

President William Clinton
Senator Arlen Specter
D. Bruce Burlington, Center Director
Jack Spears, Editor Modern HealthCare
Gene Parks, President HealthCare Imaging

Tom Quinn
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