

808 Richmond Ave. - Unit 1
Staunton, VA 24401-4955
Local (540) 886-2926
Fax (540) 886-3103
Toll-Free (800) 770-7732

March 9, 1998

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

To Whom It May Concern,

This letter is to express our opinion regarding whether or not, refurbishers, rebuilders, reconditioners, servicers, and "as is" marketers of medical devices should fall under GMP regulations.

I have personally sold hundreds of pieces of professionally reconditioned hospital and medical equipment since 1983. During that time, we have never had a customer refuse to accept a piece of equipment, had any complaints from customers, or had any items returned due to poor quality. We have always clearly labeled and identified the equipment as reconditioned. We have always had an independent, qualified biomedical shop certify the equipment with regards to safety and performance. We have also never deviated from the original OEM specs, except for any upgrades that were developed by the manufacturer.

If a "secondary marketer" follows these guidelines, where's the problem? We don't see any. We might suggest that the reseller notify the OEM who owns the item now so any recalls, bulletins, and other important information could be sent directly to the new owner, instead of the original "owner-of-record."

Our firm was inspected by Karen Anthony from your Richmond, VA office in April of 1997 and found to be in compliance. We would welcome this sort of inspection in the future and are glad to cooperate in any way we can. Please let me know if we can provide any further information.

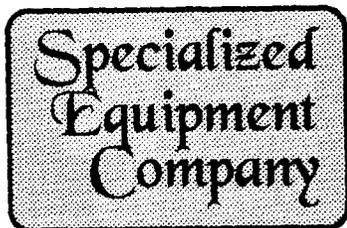
Sincerely,

A handwritten signature in cursive script that reads "Mike".

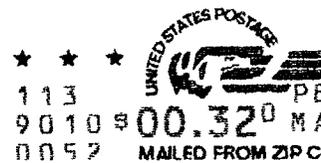
Michael Obenschain
President
1998 Registration # 1123809

97N-0477

C14



808 Richmond Ave. - Unit 1
Staunton, VA 24401-4955



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

