

B.B.S.

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

Re: Document # 97N-0477
Refurbishers, Rebuilders, Reconditioners, Servicers, etc.

- We agree substantially with definitions within this document.
- We are disappointed to date that **THE** major contributing factor to poor device maintenance within our health care system and the rest of our national health care network is **INADEQUATE and NONEXISTENT SERVICE, PARTS, AND MAINTENANCE DOCUMENTATION**; be that from Manufacturers, Remanufacturers, Rebuilders, et al. Equipment once purchased belongs to and is the responsibility of the owner. Manufacturers have practically no responsibility under current FDA reg's to support that equipment once purchased.

Sincerely,



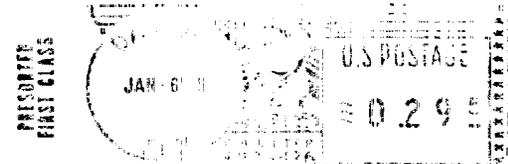
Jeff L. Butler, P.E.
Director / C.O.O.

97N-0477

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