



THE BOC GROUP

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February 13, 1998

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

Subject: Refurbishers, Rebuilders, Reconditioners, Services and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information  
FDA Docket Number 97N-0477

Dear FDA:

Pursuant to the request published in the Federal Register, volume 62, number 246, page 67011-67013, Ohmeda Medical Systems Division (MSD) hereby submits written comments and information on FDA Docket Number 97N-0477. This request pertains to Refurbishers, Rebuilders, Reconditioners, Servicers and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements.

To aid review, the comments and information provided below from Ohmeda MSD have been separated into general comments, specific comments and recommended applicable regulatory requirements of the cGMP (Quality System Regulation) and other appropriate regulations.

General Comments

- Third party refurbishers, as is remarketers and servicers have a greater potential to compromise patient safety due to their lack of regulatory control when compared to remanufacturers.
- This lack of regulatory control provides a distinct competitive advantage to third party refurbishers, as is remarketers and servicers in the marketplace.
- The policy guides and regulatory requirements that are developed from these comments should only address the resale or redistribution of these medical devices.
- The servicers definition should be removed since it does not apply to the resale or redistribution of these devices.
- The self servicers (internal healthcare facility servicers) should be exempt from regulation.

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Specific Comments

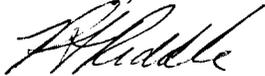
- The medical devices should be specifically labeled to identify if they have been remanufactured, refurbished or remarketed as is by the entity performing the activity. This label would also include the name and address of the entity performing the activity. This allows the customer to clearly identify the level of activity conducted.
- The “remanufacturing” definition contained in the cGMP (Quality System Regulation) should remain unchanged.
- The refurbishers definition should be revised to state “persons who, for the purpose of resale or redistribution, visually inspect, functionally test and service devices, as may be required, to demonstrate that the device is in good repair and performing all the functions for which it is designed and originally labeled. Preventative maintenance procedures shall be performed. Refurbishers do not significantly change the performance or safety specifications, or intended use of a finished device.”

Regulatory Requirements

- |                     |          |  |
|---------------------|----------|--|
| • Remanufacturers   | 21CFR803 | Subpart E  |
|                     | 21CFR807 | Subpart B  |
|                     | 21CFR820 | Subpart A, B, C, D, E, F, G, H, I, J, K, L, M, N |
| • Refurbishers      | 21CFR803 | Subpart E  |
|                     | 21CFR807 | Subpart B  |
|                     | 21CFR820 | Subpart B, D, F, G, H, I, J, K, L, M, N          |
| • As Is Remarketers | 21CFR803 | Subpart E  |
|                     | 21CFR807 | Subpart B  |
|                     | 21CFR820 | Subpart D, F, G, H, J, K, M, N                   |
| • Servicers         | 21CFR803 | Subpart E  |
|                     | 21CFR807 | Subpart B  |
|                     | 21CFR820 | Subpart D, F, G, K, M, N                         |

Ohmeda MSD appreciates the opportunity to provide comments and information. It is hoped that these comments will be used to develop effective policy guides and regulatory controls. If there are any questions or comments, please contact me.

Sincerely,



Raymond T. Riddle  
Divisional Manager, Regulatory Affairs

c.c.: Bill Exner  
Neal Sandy

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