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January 29, 1998

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

Re. **Docket No. 97N-0477**

Medical Devices; Refurbishers, Rebuilders, Reconditioners, Servicers, and "As Is" Remarketers of Medical Devices; Review and Revision of Compliance Policy Guides and Regulatory Requirements; Request for Comments and Information

To Whom It May Concern:

This letter is being written and submitted on behalf of my clients, who manufacture, market, and service medical devices. These clients market electronic devices that are life sustaining and life supporting. These devices include; Anesthesia Machines, Ventilators, Incubators, etc.

My clients support the need for a Compliance Policy Guide (CPG) of this nature and the enforcement of CPG 7124.28. However, we do have some concerns regarding the proposed definitions in this Notice. Specifically we would like to point out the following:

1.0 If a Refurbisher, As Is Remarketer, or Servicer is not trained by the original manufacturer, even seemingly minor alterations may effect the performance and/or safety of a device. Thus, in all three proposed definitions, unless the Refurbisher, As Is Remarketer, or Servicer is a part of the original manufacturers organization, or is trained and licensed by the original manufacturer, the firm would have no way of knowing if the changes that they make could affect the performance and/or safety of the device.

2.0 Because of the above, we suggest that there be two classes of these definitions.

2.1 The first class would be those firms that are either part of the original manufacturers organization or who have been trained and licensed by the original manufacturer. The proposed definitions would be applicable to this class of firm.

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2.2 The second class of firms would be those firms not affiliated with the original manufacturer. The work performed by these firms should be limited to the preventative maintenance listed in the original manufacturer's manuals for the specific device. Any work performed by these firms, not listed in the manuals, should be subject to the premarket notification requirements of the Act and Regulations.

Specific examples of actual problems created by Refurbishers, As Is Remanufacturers, or Servicers on my clients products are difficult to detail and prove. However, we have had several instances where changes have been made to devices that resulted in the submission of Medical Device Reports. These changes were of the type that are not sanctioned by my client. In each of these instances, the Users would not confirm or deny that another firm or their own personnel made the changes. We would like to point out that our trained field service personnel are only sanctioned to perform repairs to a certain level. If the device requires additional service, these individuals are instructed to return the device to my client's main office for the repair. This had obviously not occurred in the above-cited instances.

We believe that Refurbishers, As Is Remarketers, and Servicers should be subject to the same requirements as the original manufacturer. These requirements are spelled out in CPG 7124.28 and should be applied to each of these types of firms. If these firms were subject to different and less restrictive requirements than the original manufacturer it would place the original manufacturer at a competitive disadvantage. It could also conceivably result in a situation where patient safety could be compromised.

Sincerely,

James R. Collie, RAC

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