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Dockets Management Branch
HFA - 305
Food and Drug Administration
12420 Parklawn Drive room 1-23
Rockville, MD 20857

March 26, 1998

Dear Sir or Madam:

I would like to raise the issue and understand how companies who repair components, boards, chases, cables, harnesses and electronics will be classified, defined and addressed under this Compliance Policy Guide and Regulatory Requirements.

Specifically, if a company has a repair center where "repairs" are considered part of the service responsibilities, what aspects of the Quality System Regulation and/or what provisions in the proposed requirements will they need to meet. This function does not "repair" the actual devices, only the components that are used by the service personnel in the field to repair the actual devices. The function is also separate from the actual device manufacturing operations.

Is this group considered separate from or distinct from the service function. The components that are repaired are brought to their original specifications, not the most current.

Is this an oversight, is it meant to be a loophole in the requirements or is the agency going to issue a separate requirement for this type of "repair" or "service".

Best Regards,



Kenneth E. Imler

97P-0477

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