



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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6/8/00

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN 1 2000

Mr. Joseph A. Mertis  
Allegiance Healthcare Corporation  
1500 Waukegan Road  
McGaw Park, Illinois 60085

Re: Docket No. 00P-1320  
Convenience Kits and Trays

Dear Mr. Mertis:

This responds to your citizen petition, dated May 8, 2000, and your follow-up letter, dated May 24, 2000, in which you request a variance from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables. We understand that certain of your firm's surgical convenience kits, trays, and procedure modules contain lead wires or cables that do not comply with the performance standard. These kits, trays and modules have been assembled to meet specific orders from individual healthcare facilities, and those facilities are awaiting delivery. Approximately 650 of the kits and trays are sterile. In addition, there are approximately 100 non-sterile procedure modules, some of which may also contain a sterile kit or tray. The kits or trays contain numerous medical devices, some of which cannot be re-sterilized, if the kits or trays are opened to replace the non-compliant electrode lead wires or cables. Therefore, your petition requests a variance to allow you to distribute these kits, trays and modules to the intended customers, and to allow those customers to use those non-compliant lead wires and cables until September 9, 2000.

I am granting your petition with regard to lead wires and cables that are in convenience kits or trays that have already been sterilized. This variance also applies to any of the procedure modules that already contain sterile lead wires or cables. However, I am denying the petition with regard to any lead wires or cables that are not yet sterilized. The non-sterilized lead wires and cables can and should be removed from the non-sterile kit, tray or module, and should be replaced with a lead wire or cable that complies with the performance standard. Healthcare facilities are permitted a single use of these sterile lead wires and cables until September 9, 2000.

As a condition of this action, I ask that you include a notice with your shipment of those sterile kits, trays and modules that are subject to this variance. The notice should clearly state the enclosed lead wires or cables are subject to an FDA-approved variance from the performance standard, but that the kit, tray or module must be used before September 9, 2000. The notice should also clarify that the lead wires or cables are not intended to be re-sterilized and reused, and that such reuse would be in violation of both this variance and the performance standard.

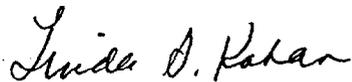
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I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

A handwritten signature in cursive script that reads "Linda S. Kahan".

Linda S. Kahan

Deputy Director for Regulations and Policy  
Center for Devices and Radiological Health