



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG - 2 2000

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Margaret A. Bench, RN  
Cardiac Rehabilitation Program Coordinator  
Bon Secours South County Heart Center  
1221 Jacaranda Blvd.  
Venice, Florida 34292

Re: Docket No. 00V-1405  
Telemetry Transmitter Lead Wires

Dear Ms. Bench:

This responds to your citizen petition, dated May 10, 2000, requesting a variance from the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) as it applies to a certain telemetry transmitter lead wires used in your facility. I apologize for our delay in responding.

The telemetry transmitter described in your petition is one of ten device types for which the electrode lead wires must comply with the performance standard on or after May 11, 1998. Your lead wires have been non-compliant for the past two years. Your telemetry transmitter uses a lead wire connector with three exposed 2 mm pins, and is therefore non-compliant with the performance standard. Your petition proposes to secure the lead wire connector to the telemetry transmitter using a nylon cord, and to also add a label on the transmitter warning against removal of the lead wire. From the pictures you provided, it appears that the nylon cord is a tie wrap that would have to be cut from the device in order to disconnect the lead wire or to replace the batteries. Your procedures call for replacement of the nylon cord, when it is removed for battery replacement. You noted that there are 24 devices with the lead wires secured in this manner, and there are eight replacement telemetry-transmitter lead wires that are now stored in a locked cabinet. You requested a variance to continue use of the non-compliant transmitter lead wires until the transmitters are either replaced or converted to accept compliant lead wires. Your petition did not identify the manufacturer of the transmitters, did not state whether you had been in contact with that manufacturer regarding availability of an adapter to convert the device, and did not specify any particular timeframe for your variance request.

I am granting a temporary variance until May 9, 2001, for you to identify an acceptable adapter and compliant lead wire for your telemetry transmitters. Note that the performance standard anticipates that by use of relatively inexpensive adapters, devices like yours can be converted to accept compliant lead wires. We believe that adapters may be available for considerably less than the \$100 per unit cited in your petition. We are aware of several lead wire manufacturers who produce adapters for individual exposed 2 mm pins, but not for the specific three-pin connector used with your transmitter. However, one of those manufacturers or the manufacturer of your transmitter may be able to provide a suitable adapter. If not, you may contact us again regarding further extension of this variance.

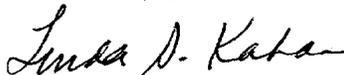
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I trust that this response fully addresses your concerns. If additional information is required, or you need further assistance in identifying potential suppliers of lead wire adapters, you may contact Mr. Stewart Crumpler in our Office of Compliance at 301-594-4659.

Sincerely yours,



Linda S. Kahan

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