DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

5254 '01 MAY 17 P1:57 MAY - 9 2001

Geoffrey L. Kirkham
Director, Materials Management
Raytel Medical Corporation
7 Waterside Crossing
Windsor, Connecticut 06095-1548

Re: Docket No. 98P-0305/EXP 1

Dear Mr. Kirkham:

This responds to your citizen petition, dated April 26, 2001, requesting a further extension of your previously approved variance from the Performance Standard for Electrode Lead Wires and Patient Cables. That previous variance was approved on April 12, 1998, and is scheduled to expire on May 11, 2001.

We understand that your firm provides remote cardiac monitoring services for patients using devices from several different manufacturers. You noted that your firm has contracted to have replacement lead wires manufactured, but you have encountered a delay regarding the lead wires needed for your Medtronic 9408 and 9431 transmitters. Your contractor has experienced a manufacturing problem that will make it impossible for you to be in full compliance by the May 11th deadline. You expect to have approximately one half of your devices retrofitted by May 11th, but you are requesting a further extension of your variance to allow time for production and distribution of the necessary replacement lead wires for the remaining devices.

I am granting your request and extending your temporary variance until August 11, 2001. I trust that this response fully addresses your concerns. If additional information is required, you may contact Mr. Stewart Crumpler in our Office of Compliance at 301-594-4659.

Sincerely yours,

Linda S. Kahan

Linda S. Kahan
Deputy Director for Regulations and Policy
Center for Devices and Radiological Health

98P-0305

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