

RAYTEL MEDICAL CORPORATION

April 26, 2001

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Stewart Crumpler
Office of Compliance
HFZ-340
Center for Devices and Radiological Health
2094 Gaither Road
Rockville, Maryland 20850

Dear Mr. Crumpler:

I am writing in response to our telephone conversation of today in regards to Dr. D. Bruce Burlington's letter dated August 12, 1998 in reference to our citizen petition, dated April 29, 1998, and our request for an extension for an additional 90 days from May 11, 2001, to August 11, 2001.

As a re-cap to our conversation I would like to provide the following information as justification towards the extension.

- We have approximately 50,770 patients that we have to provide the new FDA compliant lead wires to.
- Raytel has already modified 7,800 units and will have 20,000 completed by the May 11th deadline.
- At issue, are the lead wires that would retrofit our Medtronic 9408 and 9431 transmitters. Raytel issued a Purchase Order for the lead wires on December 6, 2000 with a commitment date in order to be in full compliance as of May 11, 2001.
- We have approximately 87,926 lead wires that are being specifically manufactured for Raytel to ensure compliance to "Performance Standard for Electrode Lead Wires and Patient Cables (CFR 898) 62 Fed. Reg. 25497; May 9, 1997)".
- The awarded manufacture "Lakewood Products, Inc., Medina, MN has had and is presently still having manufacturing and production problems. Please note the attached letter from Mike Fanberg, President Lakewood Products, Inc dated April 25, 2001 to Paul Ricci of Raytel Cardiac Services.
- Total cost to Raytel for material, labor and shipping will exceed \$671,025.00



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EXP 1

It is the combination of all the above factors that brought us to the point of frustration and my phone call to you to day requesting the 90-day extension.

Thank you for your guidance today on the phone and your interest and help in this matter. If you have any questions, I can be reached at (860) 298-6100, ext. 646.

Sincerely,



Geoffrey L. Kirkham
Director Materials Management

Encl.: E-Mail Letter, Lakewood Products, Inc.

Cc: file

April 25, 2001

Mr. Paul Ricci
Raytel Cardiac Services
7 Waterside Crossing
Windsor, CT 06095

Dear Paul

Since receiving your purchase order for 60,000 shunt cables we have been trying to meet your schedule. Tooling was completed the end of January however, the resin we planned to use was not hard enough to insure that the plug protectors could not be distorted and thereby circumvented by the user. We spent about one week working with our supplier determining the proper resin, and then waited ten days to receive the first shipment. Normally a plug like this would be molded in two operations, the inner mold, a soft plastic which will not harm the solder joints and then the outer harder plastic would be over molded. In an effort to save money in tooling as well as to produce these parts quickly we choose to do this in one step. This process is working fine now, however, it took a week or so to eliminate failures. Once we got the resin and these problems worked out we began shipments of the first part, numbers LP001364-003 and -004.

At this same time we had been recruiting people to manufacture these parts. This proved to be our most serious problem and it continues to be, to date. We had an extremely tight job market in Minnesota through-out the winter, this problem is easing but still remains our biggest manufacturing problem.

While we were searching for employees we were also attempting to find an outsource to solder the plugs onto the wire. This is the most difficult and time consuming part of the production process. On March 26, 2001 I met with people from a company in St. Paul MN., called Eagan Technical Services who accepted a purchase order to produce 1000 parts per day beginning the first week in April. Their first samples were not too good but after working with them I felt they could do the job. Their first shipment was for 450 wires, however, 30% to 40% of these were rejected for several reasons including sloppy workmanship, no continuity etc. I met with them again and went over the process and what our expectations were, and they made another 500 pieces. This second lot was not much better than the first. As a result they agreed to fix the problems and replace the bad parts. The next week Eagan Technical called and said they would not be able to continue with the order because our quality requirements were too stringent and they would lose money at the price they had quoted. I might add here, that they had already raised their price by 20% after the first attempt at soldering the part.

Some of the components that are used in these cables are purchased from Minnesota Wire and Cable company. I had spoken with their buyer about the same time I was talking to Eagan Technical, and he mentioned that they had availability in their plant and if they

could be of service to let them know. I felt sure we had the problem solved so I did not pursue the offer. I have since received a quote for MN. Wire, and am sending them parts to begin soldering the plugs. They are very familiar with the plug and wiring configuration as they at one time supplied Instomedix with a very similar design. Minnesota Wire can complete 10,000 wires per week beginning the first week of May. We will strip and prep the wire for them and they will solder the plug side of the part. We will continue to solder plugs and all of the snaps.

In addition to this company we have contacted another company we have done business with for about 10 years. They are a similar to us in that they manufacture medical cables for many companies. They are looking at the project and will be getting back to me next week.

I realize that an additional 10,000 parts per week does not make up the shortfall we are facing. I believe that with the help of Minnesota Wire we can finish the project by June 22, 2001. If I can hire another company to help we may be able to cut that by three weeks to June 1st.

I regret the position we have put Raytel Cardiac services in. Please be assured we are doing everything in our power to correct the situation.

Sincerely,

Mike Fanberg
Lakewood Products, Inc.