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February 21, 2001

Dockets Management Branch
Food and Drug Administration
Department of Health & Human Services
Rm. 1-23
12420 Parklawn Dr., Rockville, MD 20857

Re: Citizen Petition - Request for Variance Electronic Lead Wires and Patient Cables

Citizen Petition: The undersigned submits this petition under 21 CFR, section 898.14m and 21 CFR, section 10.30 to allow a variance that extends the deadline for full implementation of the requirements outlined in the Code of Federal Regulations, Chapter 21, Part 898 which became effective for certain medical devices on May 11, 1998.

Action Requested: On May 4, 1999, Idaho Cardiology Associates, P.A. (ICA) requested that the Commissioner allow a variance to allow sufficient time to allow modification and/or replacement on two medical devices it currently had in its inventory:

1) Instromedix brand (models KOH 300 and KOH 600) cardiac monitors. ICA currently has 17 Instromedix KOH 300/600 units in inventory. We have contacted Entech Corporation, and they have been able to provide a modification to the units that will bring them into compliance with the referenced international standard, IEC 60601-1. Status: **Completed**. ICA has completed replacement or modification these units.

2) TZ Medical Inc. brand telephone pacemaker transmitters and receiver units. ICA originally reported that it had 120 of these units currently in the field in use by its cardiac patients. According to TZ Medical, there is no adapter modification available for these units and will have to be replaced with new units that conform to the standard. In May 2000, ICA consolidated all telephone pacemaker transmission units to our arrhythmia center. At that time, we discovered a May 1999 error in counting and ICA actually still had over 700 units in the field that did not meet the Standard. During FY 2000, we steadily replaced the units at a rate of 50 per month, except for November and December when the manufacturer could not deliver our orders. Currently, we have 246 units left in service and plan to complete replacement with new units by the end of September 2001. Currently, ICA is in the process of recalling all affected units in small numbers each month and replacing the affected units with the new compliant units.

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Statement of Grounds: Our original request for variance was done in consult with Mr. Stuart Crumpler at the FDA/CDRH Office of Compliance, Division of Enforcement III, the device manufacturer's and the biomedical repair firm of Entech Corporation. Since the grant of the original variance on November 24, 1999 (Docket No. 99V-1308), ICA has been working to replace the affected units. Because of the larger number of these units in service than we originally reported, ICA specifically requests a four month extension (October 1, 2001) to the original variance to allow time to complete replacement of the affected units without undue financial burden on the medical practice. ICA requests that an extension of the original variance be granted based on four factors:

1. Cost impact to the practice.

2. Non-availability of adapters in the market place to provide a cost-effective solution to the problem.

3. Prior approval of similar variances to other medical groups/hospitals who are experiencing the same difficulties with replacement of pacemaker transmitters.

4. ICA has diligently worked to remove the affected units from service and replace them with compliant telephone pacemaker transmitters. A four month extension will allow orderly completion and minimize economic impact on the practice.

Environmental Impact: None.

Economic Impact: The cost to replace the remaining 246 TZ Medical Inc. brand telephone pacemaker transmitters and receiver units is approximately $14,514. The economic impact on ICA would be mitigated by the approval of this variance.

Certification: The undersigned certifies, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature _____

Name of Petitioner Roy Tweedle for Idaho Cardiology Associates, P.A.
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