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6977 '99 MAY -7

May 4, 1999

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: Idaho Cardiology Associates, P.A. (ICA) requests the Commissioner allow a variance to allow sufficient time to allow modification and/or replacement on two medical devices it currently has 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. ICA currently is in the process of rotating these units out of service and sending each to Entech for modification.
- 2) TZ Medical Inc. brand telephone pacemaker transmitters and receiver units. ICA has 120 of these units currently in the field being used by its cardiac patients. According to TZ Medical, there is no adapter modification available for these units and that they will have to be replaced with new units that conform to the standard. 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.

99V-1308

VAR 1

Statement of Grounds: 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, ICA has been working to bring both of the medical devices referenced above into compliance with the directive. Because of the number of these units in service, ICA specifically requests a variance to allow time to implement the corrective action without undue financial burden on the medical practice. ICA requests that a variance be granted based on three 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 the King of Hearts monitors and pacemaker transmitters.

Environmental Impact: None.

Economic Impact: The cost to replace the affected Instomedix KOH 300/600 units is \$10,115 versus cost to modify all units will be \$2,550. The cost to replace 120 TZ Medical Inc. brand telephone pacemaker transmitters and receiver units is approximately \$6,000. 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.

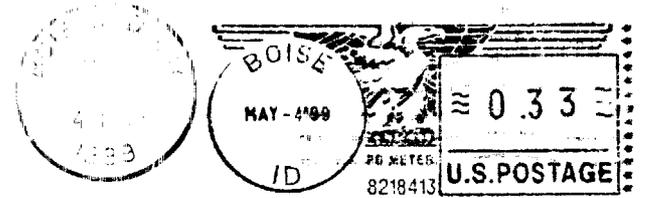
Signature _____

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

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