



1714 '00 MAR 20 19:12

March 9, 2000

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



Re: Citizen Petition 00P-0498/CP 1

Request for Exemption for the Swan-Ganz Pacing Catheters and Probes

This document is submitted in response to a request from Kent Berthold, Consumer Safety Officer, Office of Compliance, for additional information regarding the referenced Citizen Petition. The following information was requested:

1. *Please provide a better description of how the Baxter Pacing catheters and probes connect with the Medtronic device.*

Attached to this letter is a document containing two illustrations. The top illustration clearly depicts the connection of the Baxter electrode connectors (on the Pacing catheters and probes) with the Medtronic cable, demonstrating the fit of the lead connectors with the Medtronic cable in their current configuration.

2. *Why can't the connectors be redesigned?*

The second illustration in the attached document demonstrates the results of redesigning the Baxter connectors to meet the requirements of the Performance

00P-0498

CI

Standard. The resulting recessed leads would not be able to interface with the Medtronic cable, leaving the Baxter devices nonfunctional.

3. *Why won't adapters work with these devices?*

If Baxter redesigns the connector to meet the requirements of the Performance Standard, an adapter would be needed to connect the Baxter devices with the Medtronic cable. The adapter would be required to have exposed leads to interface with the Medtronic cable, thus presenting the same problem that currently exists with the Baxter products. The use of an adaptor, therefore, would not reduce the risk associated with these devices.

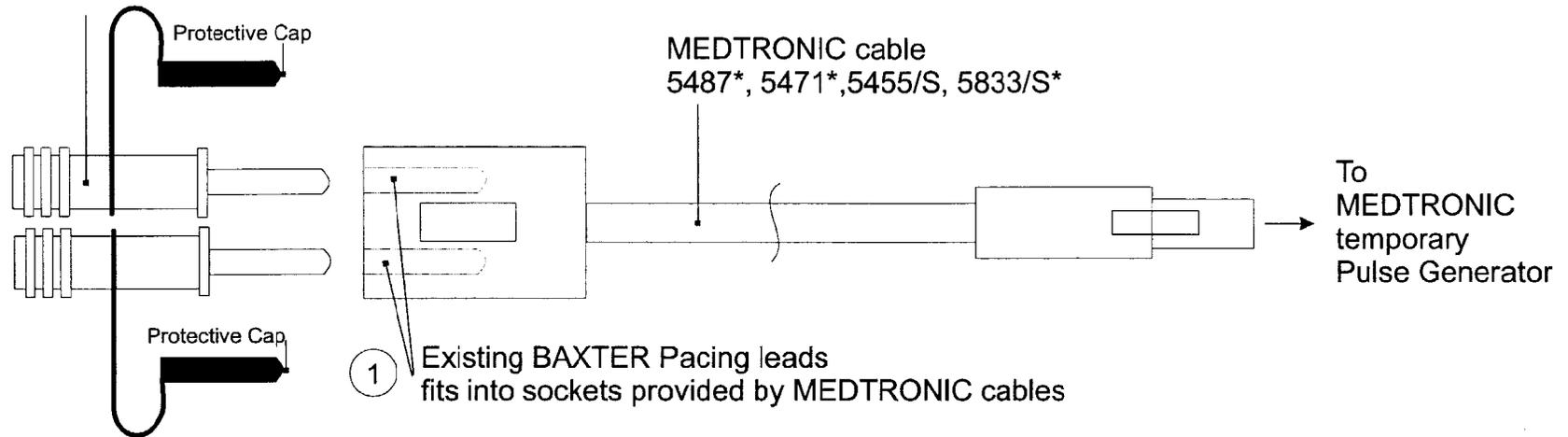
The information provided should adequately address your questions regarding the Petition. If you have any further questions, please feel free to call me at (949) 250-2418.

Sincerely,



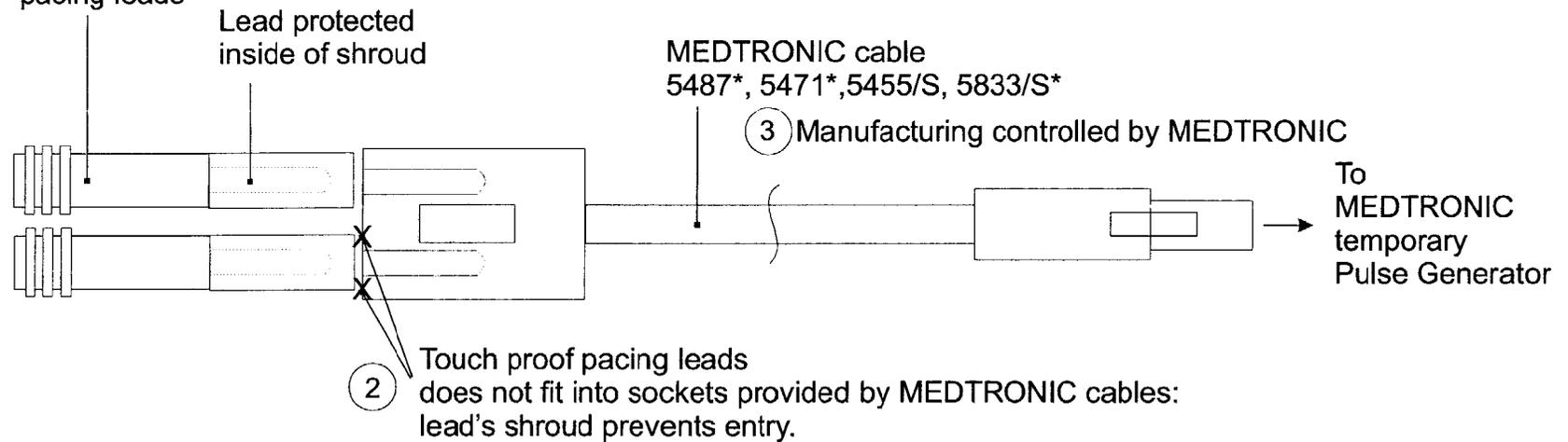
Paula A. Torrianni
Manager, Regulatory Affairs
CardioVascular Group

Existing
BAXTER Pacing leads



Connection between Current BAXTER pacing leads and MEDTRONIC pulse generators

Touch proof
pacing leads



Issue encountered in mating touch proof pacing leads to MEDTRONIC pulse generators