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Dean Bruhn-Ding
Director of Regulatory Affairs and Quality Assurance
Daig Corporation
14901 DeVeau Place
Minnetonka, Minnesota 55345

RE: Citizen Petition 99-5519

Dear Mr. Bruhn-Ding:

This responds to your letters, dated December 16, 1999 and February 15, 2000, in which you requested an exemption from the Performance Standard for Electrode Lead Wires and Patient Cables, as it applies to your firm's Pacel temporary pacing catheters. We are denying your request based on the availability of a suitable adapter solution that can be used to satisfactorily remedy the concerns raised in your citizen petition. In the Statement of Grounds for your petition, you provided several arguments that we have carefully considered but rejected. Our rationale is explained below.

As you know, exposed-pin lead wires may not be marketed or used after May 9, 2000, without an approved exemption or variance. The Food and Drug Administration (FDA) has granted exemptions from the performance standard for certain electrosurgical electrodes, for all heart wires, and for a few Medtronic pacing and stimulation electrodes that cannot comply with the performance standard. Several of those exemptions involve a very small gauge lead wire that is introduced through the lumen of a catheter or a needle. The catheter or needle is then withdrawn over the distal end of the lead wire. However, it appears from your labeling that the Pacel catheter remains in place and is not withdrawn during the clinical procedure. No clinical rationale was presented to show why the Pacel catheter cannot be made to comply with the performance standard, and still perform as intended.

You noted that manufacturers of external pacemaker generators are not bound by the performance standard. While external pacemaker generators are not themselves subject to the standard, their manufacturers should be highly motivated to provide a capability to accept protected lead wire connections. FDA has notified manufacturers and they should all be aware that (absent an approved exemption or variance) unprotected lead wires cannot be legally marketed or used with their devices after May 9, 2000. To the extent that multiple device manufacturers can standardize a common connector configuration (as they did previously with 2 mm exposed pins), the industry can help to alleviate confusion. In the meantime, we expect that user facilities will make choices from among vendors (just as they have in the past) and will have the appropriate adapters available that are suitable for use with

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their particular pacemaker generators and lead wires. Under those circumstances, there should be minimal confusion in any individual healthcare facility regarding compatibility.

Arguments similar to yours, regarding proximity to AC current and likelihood of injury, were considered during promulgation of the performance standard. Likewise, labeling alternatives were considered but rejected in favor of a mechanical safety solution. The preamble to the final rule states that FDA expects adapters will be developed so that existing equipment can be converted to accept protected lead wires. In response to your February 15th inquiry, let me also assure you that such adapters and adapter cables may continue to be marketed after May 9, 2000, and until such time as they are no longer needed. I understand from your conversation with Mr. Stewart Crumpler that Daig has designed an adapter that will convert an external pacemaker generator to accept your DIN-style shrouded pin connector. We believe that your adapter, and similar adapters from several other vendors, can be successfully used to convert existing temporary pacing equipment in healthcare facilities. We are not aware of any data to show increased risks posed by the potential for electrical discontinuity, and your petition did not provide such data. We understand that a single, universal adapter may not be feasible, but each healthcare facility can standardize on a particular adapter solution, just as they currently choose from among the many different types of connectors currently on the market.

You spoke with Mr. Crumpler about how your adapter needs to be secured permanently to the device. In our past discussions with manufacturers and user facilities, the Office of Compliance has emphasized that an adapter needs to be secured to the device in such a way that the adapter cannot be inadvertently removed when the lead wire is disconnected. Easy removal of the adapter with the lead wire could reconvert a compliant lead wire back to an unsafe configuration, thus defeating the safety intent of the performance standard. FDA has generally advised manufacturers that the adapter should either be permanently attached to the device, or removable only by use of a tool. However, we understand that older external pacemaker generators and some new interface cables typically have a thumbscrew, collet, or chuck that is manually tightened onto an exposed-pin lead wire to secure it in place and to provide good electrical contact. The use of this same thumbscrew, collet, or chuck to manually secure an adapter to the device or to an interface cable, would meet the intent of the performance standard. In these circumstances, removal of the adapter from the device would require a conscious decision and action by the user, and would involve more than simply pulling out the lead wire.

For pacemaker generators that are converted using adapters, user facilities can manually remove the adapters when they expect to use exempted electrode lead wires and secure the adapter back onto the device for other uses. Alternatively, some pacemaker generators (e.g., Pace Medical) provide two separate sets of collets. In those cases, the user facility can use adapters for one set of collets for use with protected lead wires, while leaving the other set of collets available for use with exempted exposed-pin lead wires.

Your February 15th letter asked several questions about the relative responsibilities of manufacturers and user facilities. User facilities have a legal obligation to convert their equipment (e.g., by using adapters) for use with lead wires that comply with the performance standard. Absent an approved exemption or variance, manufacturers cannot continue to supply non-compliant lead wires (or catheters) to these customers, so there is a tremendous incentive for user facilities to make the appropriate conversion. Manufacturers of adapters, (such as Daig) have an obligation to understand their customer's equipment, including whether there is or is not a capture mechanism, and to provide adapters that meet the safety intent of the performance standard, as described above. Where the customer's device has no existing capture mechanism, it is incumbent upon adapter suppliers to provide for such a capability with any adapters they market. If no such adapter with the appropriate capture mechanism is available from any adapter vendor, then a variance request may be submitted to FDA.

I trust that this response fully addresses your concerns. If additional information is required, please contact Stewart Crumpler in our Office of Compliance at (301) 594-4659.

Sincerely yours,

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

Draft:ESCrumpler:2/15/2000
Review:DWSerra:2/16/2000
Review:LDSpears:2/17/2000
Review:CEUldriks:2/18/00
Init:Jsheehan:2/22/00
t/f:Culdriks:2/23/00

cc: HFA-305 (Docket #99P-5519)
HFA-224
HFR-CE300
HFZ-1
HFZ-3
HFZ-15 (JSheehan, MHanna, Files)
HFZ-141 (RWalchle)
HFZ-300
HFZ-305 (Precedent Correspondence)
HFZ-340 (SCrumpler, Files)
HFZ-341

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