



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

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Robert J. Klepinski
Senior Legal Counsel
Medtronic, Inc.
Law Department MS300
7000 Central Avenue NE
Minneapolis, Minnesota 55432-3576

Re: Docket No. 98P-0330

Dear Mr. Klepinski:

This responds to your letter, dated March 9, 2000, in which you clarified your citizen petition, Docket No. 98P-0330 concerning heart wires. In response to your petition, FDA granted a categorical exemption for all "heart wires" from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables. However, there was confusion over our use of the term "breakaway myocardial needle." We now understand that the pacing industry uses the terms "distal" and "proximal" in relation to the pacing equipment, whereas FDA has used those terms in relation to the patient. This confusion led us to inappropriately refer to the myocardial needle in granting your petition request. Our intent, and yours, was that the exemption applies to any heart wire with a breakaway needle that is intended to pass from inside the patient, through the chest wall to the outside.

If additional information is required, please contact me at (301) 594-4659.

Sincerely yours,

Stewart Crumpler

Stewart Crumpler
Division of Enforcement III
Office of Compliance
Center for Devices and Radiological Health

98P-0330

LET 1

Draft:ESCrumpler:3/22/2000
Review:CEUldriks:3/22/2000
t/f:esc:3/24/2000

ESC 3/24/2000

cc: HFA-305 (Docket #98P-0330)
HFA-224
HFR-CE300
HFZ-15 (JSheehan, MHanna, Files)
HFZ-141 (RWalchle)
HFZ-300
HFZ-305 (Precedent Correspondence)
HFZ-340 (SCrumpler, Files)
HFZ-341
HFZ-450 (BZimmerman)



Medtronic

Robert J. Klepinski
Senior Legal Counsel

March 9, 2000

Mr. Stewart Crumpler
Food and Drug Administration
Office of Compliance, CDRH
Mail Code HFZ-340
2094 Gaither Road
Rockville, MD 20850

RE: PETITION DOCKET NO. 98P-0330

Dear Mr. Crumpler:

Medtronic wishes to clarify the wording of the exemption granted in regard to our Petition Docket No. 98P-0330. At the end of your letter granting the petition, you describe the exempted products as "temporary pacemaker electrodes that include myocardial needles used during open chest surgery." As we discussed in our telephone conversation, the "myocardial" part of that is not descriptive of the needle that passes out through the chest wall but rather of the needle at the other end of the heart wire described in the Petition. Some of our heart wires do not have myocardial needles, but rather are introduced through a vein into the heart.

A copy of a picture of one of these devices is attached.

As we discussed in our telephone conversation, the confusion in this area resulted from my selection of terminology. You explained that in the cable world "distal" meant distal to the patient in this context. Therefore, the proximal end would be the end attached to the patient, and the distal end would be the portion sticking out of the patient. In the pacemaker/lead world "proximal" usually refers to the part of the lead attached to the pacemaker, and "distal" refers to the end that is delivering electrical impulses to the patient. I used improper terminology in this context. I was using the terminology used on the other implantable products. Therefore, my reference to the distal myocardial needle resulted in the language in the letter.

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Mr. Stewart Crumpler
March 9, 2000
Page Two

We would like clarification that the exemption covers all of our devices that have the break off needle described in the petition which are passed through the chest wall from the inside of the patient to the outside. As we also discussed on the phone, these needles are used so that as small as possible hole is made in the chest wall. There is a greater risk of infection if they are passed through the original incision and are sewn up around them. This is true for all such devices whether there is a myocardial needle on the patient proximal end or endovascular lead on the patient proximal end.

We believe both our intent and yours was that all the devices having the break off through-the-chest needle on the distal end were covered by the exemption. Would you please confirm that this is your interpretation of the Petition?

Thank you for your help in this clarification.

Sincerely,

MEDTRONIC, INC.

Robert J. Klepinski
Senior Legal Counsel

RJK/llg

Attachment

cc: Chuck Sidebottom

