

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Mr. Steve Jwanouskos  
 Boston Scientific EP Technologies, Inc.  
 2710 Orchard Parkway  
 San Jose, California 95134

JUN 22 2000

0660 70 JUN 26 2000

Re: Docket No. 00P-1304  
 Electrophysiology Catheters

Dear Mr. Jwanouskos:

This responds to your citizen petition, dated May 18, 2000, requesting a variance from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables for your firm's cardiac ablation catheters, diagnostic electrode recording and pacing catheters and associated cables. For purposes of this letter, these devices will be referenced as electrophysiology (EP) catheters and cables. While your variance also included cardiac ablation system instruments, note that only electrode lead wires and patient cables are subject to the performance standard – not the instruments to which they are attached.

Your petition asked that you be allowed to continue distributing EP catheters and cables with unprotected 2 mm pin connectors until November 15, 2000. You noted similar variances that FDA has granted to other manufacturers because we were concerned about the potential for shortages of EP catheters in healthcare facilities. You asked for a similar variance to allow your firm to ship EP catheters and cables from your current inventory of non-compliant devices. You noted that you are continuing to remanufacture the devices in this inventory to bring them into compliance, and that you would ship non-compliant devices only if there were inadequate quantities of compliant devices to meet customer demand. You also proposed to notify each user prior to shipment of the non-compliant device and to add a warning label to the device package to clearly identify that the device does not comply with the performance standard.

I am granting your petition, but for a shorter time frame than requested. Until August 15, 2000, you may continue to ship in stock EP catheters and cables that do not comply with the performance standard, provided there are insufficient quantities of compliant EP catheters and cables to meet customer demand. In addition, user facilities may continue to use these non-compliant EP catheters and cables until August 15, 2000. Your notification to customers, as well as your warning label on the package, should be amended to include a statement that the device cannot be used after August 15, 2000.

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

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00P-1304

FILE  
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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ	W. Jwanouskos	6/13/00						
HFZ	Stewart Crumpler	6/14/00						
HFZ	Linda S. Kahan	6/24/00						

cc:

HFA-224

HFA-305 (Docket No. 00P-1304)

HFR-PA100

HFZ-1

HFZ-215 (JSheehan, MHanna, Files)

HFZ-141 (RWalchle)

HFZ-300

HFZ-305 (Precedent Correspondence)

HFZ-340 (SCrumpler))

HFZ-341

HFZ-450 (BZimmerman)

Draft:ESCrumpler:6/13/2000

Review/Edit:CEUldriks:6/13/00

F/t:Cfrye:6/15/00

Boston Scientific.ltr

Doc. Track # 83393