

HFA-305



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

0253 '00 MAY 11 A9:46

MAY 9 2000

Marcia C. Leatham, MD  
VP, Clinical, Quality Regulatory  
Biosense Webster, Inc.  
3333 Diamond Canyon Road  
Diamond Bar, California 91765

Re: Docket No. 00P-1265  
Electrophysiology Catheters

Dear Dr. Leatham:

This responds to your citizen petition, dated April 20, 2000, and a FAX message dated May 2, 2000, requesting a 60-day variance from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables for your electrophysiology (EP) catheters. We understand EP catheters to include both diagnostic mapping catheters and therapeutic ablation catheters. Your petition asked that you be allowed to continue distributing EP catheters with unprotected pin connectors from your current inventory until July 9, 2000. At the same time you will be reworking that current finished goods inventory to bring remaining catheters into compliance with the performance standard. You noted that you have experienced supplier delays regarding protected connectors for your catheters and interface cable. You also stated that your firm will not be manufacturing any additional non-compliant EP catheters on or after May 9, 2000, except those that are specifically intended for export.

You have presented evidence that your firm supplies approximately 50% of the diagnostic mapping catheters and approximately 50% of the therapeutic ablation catheters in the U.S. You claim that your competitors are not likely to be able to meet increased product demand, if during the next 60 days, you are not allowed to distribute from your current inventory of EP catheters with unprotected pin connectors. Your petition also claims that your firm was confused regarding applicability of the Food and Drug Administration's "Guidance on Electrosurgical Devices and the Application of the Performance Standard for Electrode Lead Wires and Patient Cables," issued on November 15, 1999. Further, you noted that you have experienced unexpected delays in securing and validating the protected pin connector needed to bring your EP catheters and cables into compliance with the performance standard.

Your petition is hereby granted, but only because we are concerned about the potential for shortages of EP catheters in healthcare facilities. Note that for a cardiac catheter in direct contact with the blood pool in the heart, FDA considers the risk of electrical shock to be significantly greater than for the active electrode of an electrosurgical device. Therefore, for purposes of compliance with the performance standard, we do not consider any cardiac catheter to be exempted as an electrosurgical device. While we understand that there could have been a

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legitimate misunderstanding regarding whether a radio frequency-powered cardiac ablation catheter is an electrosurgical device, we do not see how that argument could have been extended to your diagnostic mapping catheters. Nevertheless, we recognize that the requested variance is necessary for both your diagnostic mapping and your therapeutic ablation catheters in order to avoid critical product shortages over the next two months.

As a condition of this variance approval, you are requested to prepare a notification letter to healthcare facilities that are your current customers. Your letter should include a copy of this approved variance. Healthcare facilities may not continue to use non-compliant EP catheters indefinitely. Your letter should remind your customers of their obligation to be in full compliance with the performance standard by July 9, 2000, and should provide your anticipated delivery schedule for compliant EP catheters. Healthcare facilities must discontinue use of non-compliant EP catheters as soon as new compliant EP catheters are received. Your notification letter should issue to your customers within 15 days of your receipt of this letter, with a copy submitted to the Office of Compliance, HFZ-340, Center for Devices and Radiological Health, 2094 Gaither Road, Rockville, Maryland 20850.

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:5/4/00  
Review:CEUldriks 5-5-00  
Review: Jsheehan 5-5-00

bcc:

HFA-224  
HFA-305 (Docket No. 00P-1265)  
HFR-PA200  
HFZ-1  
HFZ-215 (JSheehan, MHanna, Files)  
HFZ-141 (RWalchle)  
HFZ-300  
HFZ-305 (Precedent Correspondence)