



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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JUN 23 2000

Dean Bruhn-Ding
Director of Regulatory Affairs & Quality Assurance
St. Jude Medical
Daig Division
14901 DeVeau Place
Minnetonka, Minnesota 55345

Re: Docket No. 00P-1349
Temporary Pacing Catheters
Electrophysiology Catheters

Dear Mr. Bruhn-Ding:

This is in response to your citizen petition, dated June 15, 2000, requesting a variance from compliance with the Performance Standard for Electrode Lead Wires and Patient Cables for the following devices:

Pacel™ family of temporary pacing catheters
Response™, Supreme™, and Livewire™ families of electrophysiology (EP) catheters.

Your petition noted a similar variance that FDA has granted to another manufacturer of EP catheters 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 that do not comply with the performance standard.

I am granting your petition in part, as it applies to the specified EP catheters, similar to our actions taken with several other manufacturers to address the potential for shortages of EP catheters in healthcare facilities. Until August 22, 2000, you may continue to ship EP catheters from your current inventory that do not comply with the performance standard, when there are insufficient quantities of compliant EP catheters to meet customer demand. In addition, user facilities may continue to use these non-compliant EP catheters until August 22, 2000.

As a condition of this variance approval, you are requested to prepare a notification letter to healthcare facilities that are your current customers. You may wish to include a copy of this approved variance. Healthcare facilities are required to be in compliance with the performance standard, and 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 August 22, 2000. 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.

00P-1349

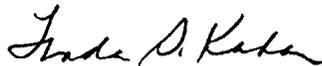
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I am denying your petition with regard to temporary pacing catheters. Unlike for EP catheters, we have granted no variances to your competitors for temporary pacing catheters. Your petition expressed your disappointment that our previous action regarding EP catheters had been taken without better knowledge of market share and the capacity of competitors to increase production to avoid widespread shortages. Your request provides information on your own short stock situation, and provides significant information regarding the relative market share of you and your competitors in the temporary pacing catheter market. However, we have no available information regarding the supply of compliant temporary pacing catheters for your competitors, or their ability to increase production to meet demand. Therefore, I am denying your request at this time. We would welcome another petition, by your firm alone, or from multiple manufacturers together, that provides more detailed information on any wide-spread stock shortages in the temporary pacing catheter market.

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