

Edwards

4554 '00 NOV 17 A8:57

November 16, 2000

Dockets Management Branch  
Food and Drug Administration  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

**RE: Citizen Petition 00P-0498/CP 1 and 00P-0498/EXP 1  
Request for Exemption for the Swan-Ganz Pacing Catheters and Probes**

On May 10, 2000, the FDA granted a four-month variance from the requirements of the Performance Standard for Electrode Lead Wires and Patient Cables (21 CFR 898) for the following products manufactured by Edwards Lifesciences (formerly known as Baxter Healthcare Corporation, Cardiovascular Group):

Model	Name
97120F5 (also provided in a kit, Model 97K12F5)	Swan-Ganz Bipolar Pacing Catheter
97130F5 (also provided in a kit, Model 97K13F5)	Swan-Ganz Bipolar Pacing Catheter
97140HF5 (kit only)	Swan-Ganz VIP Bipolar Pacing Catheter (includes a venous infusion port (VIP) for infusion of solutions)
98100 and 98100H	Chandler Transluminal V-Pacing Probe
98500 and 98500H	Flex-Tip Transluminal A-Pacing Probe
200F7, 200HF7, 205HF7	Swan-Ganz Pacing-TD Catheters

Due to issues related to our component supplier's inability to meet our timelines for completing the tooling fabrication activities and providing compliant lead components, Edwards requested an extension to this variance and was granted a 120-day extension on September 5, 2000.

00P-0498

EXP 2

Edwards has received components and has completed the required qualification/design verification activities for the impacted devices. However, receipt of a sufficient supply of these components to complete manufacturing all models listed in the variance will not occur within the deadline of January 9, 2001. The Swan-Ganz Pacing-TD Catheters will not be manufactured by the termination of the variance on January 9, 2001.

Edwards is hereby submitting a request to extend the variance an additional 60 days for the Swan-Ganz Pacing-TD Catheters, Models 200F7 and 200HF7, to allow sufficient time to manufacture compliant product for commercial distribution. Edwards continues to hold the majority of the market share (> 50%) for these types of devices. Given the critical care setting in which these catheters are used and lack of sufficient numbers of alternative compliant devices, restricting the availability of these type devices to the clinical community could pose a serious risk to the public health.

Thus, Edwards Lifesciences requests that a 60-day extension of the variance be granted to these catheters.

Should you have any questions, please feel free to call me at (949) 250-2418 or Diane Peterson at (949) 250-3514.

Sincerely,



Paula A. Torrianni  
Manager, Regulatory Affairs

Align to

EDWARDS LIFESCIENCES  
BAXTER HEALTHCARE CORP. -CUG  
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IRVINE, CA 92606

SHIP DATE: 16NOV00  
ACC # 100046473

ACTUAL WGT: 1 LBS SCALE

(714)250-2500

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Room 1061  
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Rockville MD 20852

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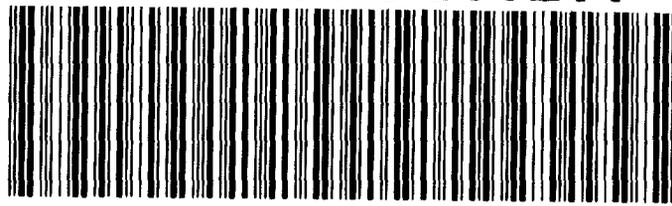
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