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AdvaMed
Advanced Medical Technology Association

July 18, 2000

via HAND DELIVERY

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Ms. Catherine P. Wentz
Division of Cardiovascular, Respiratory and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Circulatory Support and Prosthetics Devices
Food and Drug Administration (HFZ-450)
9200 Corporate Boulevard, Room 220Q
Rockville, MD 20850

Re: Medical Devices; Reclassification of 38 Preamendments Class III Devices into Class II; Comments on "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions," Docket Number 99N-0035

Dear Ms. Wentz:

I am writing on behalf of the Advanced Medical Technology Association ("AdvaMed"), formerly the Health Industry Manufacturers Association ("HIMA"), to submit two copies of comments on FDA's "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions," in response to the Food and Drug Administration's request for such comments. AdvaMed coordinated and prepared these comments through a working group. The AdvaMed Working Group ("Working Group") includes the following members: COBE Cardiovascular, Inc., Medtronic Perfusion Systems, Terumo Cardiovascular Systems Corp., and Edwards Lifesciences.

In March 1999, FDA published a proposed rule reclassifying 38 preamendment Class III devices into Class II and to establish special controls for these devices; among these devices was the Extracorporeal Blood Circuit Defoamer ("Defoamer"). See 64 Fed. Reg. 12774 (March 15, 1999). The AdvaMed Working Group ("Working Group") concurs with FDA's proposed rule reclassifying these devices from Class III to Class II because the risks related to this device are

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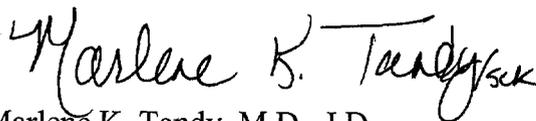
well-characterized and well-understood and special controls can reasonably assure the safety and effectiveness of Defoamers with regard to such risks.

In the above-referenced guidance issued by FDA on February 21, 2000, FDA proposed special controls for Defoamers. On April 19, 2000, the agency reopened the comment period to the public to comment on the special controls described in FDA's "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions." See 65 Fed. Reg. 20933 (April 19, 2000). This comment is submitted pursuant to the April reopening of the comment period.

The Working Group recommends that FDA revise some of the special controls delineated in this guidance. For your convenience, we are describing the proposed changes in Attachment 1, providing a red-lined copy of the guidance at Attachment 2, and providing a clean copy of the guidance with the changes incorporated at Attachment 3. Additionally, the Working Group thinks it is critical that the Guidance address human factors issues and, therefore, recommends that FDA adopt the Centrifugal Pump Bypass Checklist as a special control and publish the Checklist with the Defoamer guidance. A copy of the Checklist is provided in Attachment 4.

If you have questions or need additional information about the proposed changes, please call AdvaMed's outside counsel for reclassification, Sandra Cohen Kalter at 202-626-2944 or Dianna Thomsen at 202-626-5594.

Sincerely,



Marlene K. Tandy, M.D., J.D.
Director Technology and Regulatory Affairs,
and Associate General Counsel

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