

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2003

Mr. Timothy R. Placek
Vice President for Regulatory Affairs and Quality Systems
MicroMed Technology, Inc.
8965 Interchange Drive
Houston, TX 77054

Re: G000091/S040
MicroMed DeBakey VAD System
Dated: May 27, 2003
Received: May 29, 2003

Dear Mr. Placek:

The Food and Drug Administration (FDA) has reviewed the supplement to your investigational device exemptions (IDE) application proposing a single-arm protocol (device to be compared against a survival to cardiac transplantation performance goal) for a pivotal clinical trial for your device system. Your supplement is approved, and you may implement that change at the institutions enrolled in your investigation in accordance with the investigational site waiver granted in our April 23, 2001 letter. Your investigation is limited to twenty (20) institutions and ninety five (95) subjects.

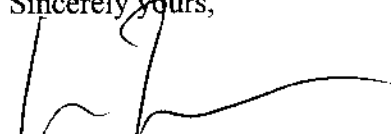
Since FDA believes this change affects the rights, safety or welfare of the subjects, you must also obtain institutional review board (IRB) approval before implementing this change in your investigation (21 CFR 812.35(a)).

We would like to point out that FDA approval of your IDE supplement does not imply that this investigation will develop sufficient safety and effectiveness data to assure FDA approval of a premarket approval (PMA) application for this device. You may obtain the guideline for the preparation of a PMA application, entitled "Premarket Approval (PMA) Manual," from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597.

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If you have any questions, please contact Michael R. Berman, Ph.D. at (301) 443-8262, ext. 161

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal flourish extending to the right.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health