



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Mr. Bill Birdsall
Chairman/CEO
Micromedical Technologies, Inc.
8965 Interchange Dr.
Houston, TX 77054

APR 15 2010

Re: H030003/S9
2002-0098
MicroMed DeBakey VAD® *Child* Left Ventricular Assist Device
Filed: March 15, 2010

Dear Mr. Birdsall:

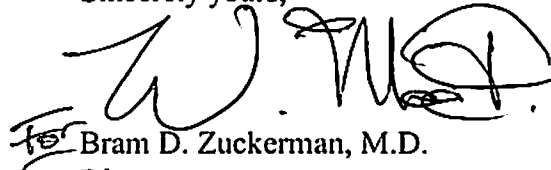
The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your humanitarian device exemption application (HDE) supplement, which requested approval for changing the device trade name from the DeBakey VAD® *Child* Left Ventricular Assist Device to HeartAssist® 5 Pediatric VAD. The device, as modified, will be marketed under the trade name HeartAssist® 5 Pediatric VAD and is indicated for use to provide temporary left side mechanical circulatory support as a bridge to cardiac transplantation for pediatric patients (5-16 years old, with BSA > 0.7 m² and < 1.5 m²) who are in NYHA Class IV end stage heart failure, are refractory to medical therapy and who are (listed) candidates for cardiac transplantation.. Based upon the information submitted, the HDE supplement is approved subject to the conditions described in the approval order for your original HDE. You may begin commercial distribution of the device as modified by your HDE supplement upon receipt of this letter.

Failure to comply with the conditions of approval as described in the approval order for the original HDE invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

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If you have questions concerning this approval order, please contact Shreya Mehta at (301) 796-0750.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman'. The signature is stylized with large, sweeping letters and a prominent flourish at the end.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health