



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 21 2008

Mr. Donald A. Middlebrook  
Vice President, Regulatory Affairs and Quality Assurance  
Thoratec Corporation  
6035 Stoneridge Drive  
Pleasanton CA 94588

Re: P060040  
Thoratec HeartMate II® Left Ventricular Assist System (LVAS)  
Filed: December 22, 2006  
Amended: January 26 and 30, February 16 and 23, March 6, July 25, August 7,  
September 24 and 28, and October 26, 2007 and February 1, 4, 5, and 11, and April  
4, 2008  
Procode: DSQ

Dear Mr. Middlebrook:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Thoratec HeartMate II® LVAS. This device is indicated for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. The HeartMate II LVAS is intended for use both inside and outside the hospital, or for transportation of ventricular assist device patients via ground ambulance, fixed-wing aircraft, or helicopter. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

In addition to the postapproval requirements outlined in the enclosure, you have agreed to provide the following in postapproval reports:

You have agreed to implement a postapproval study that will enroll 338 patients. These patients will include the first consecutive 169 HeartMate II patients who give their consent for inclusion in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) registry and an equal number of patients from the concurrent patients enrolled in INTERMACS. The patients will be followed in the postapproval study until study outcome: transplant, death or explant for recovery. There will also be an assessment at one year post explant. A detailed protocol, including but not limited to, patient characteristics at the time of implantation, incidence of adverse events (including definitions) while being supported by the device system, patient outcome(s), standardized anticoagulation protocol, quality of life assessment tools, functional status instruments, and the proposed reporting interval (e.g., 6 months) will be collected. Furthermore, you have agreed to collect data regarding both gender and body surface area to determine if differences exist in the safety and effectiveness of the device in these populations and data regarding the relationship between bleeding and anticoagulation in all patients. The postapproval study enrollment will begin immediately upon FDA approval of the HeartMate II® LVAS as a bridge to cardiac transplantation

Expiration dating for this product has been established and approved at 3 years.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at <http://www.fda.gov/cdrh/pmapage.html>. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

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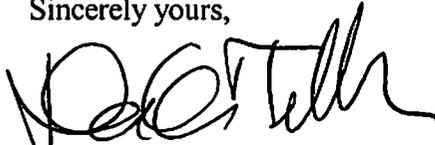
You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)  
Center for Devices, and Radiological Health  
Food and Drug Administration  
9200 Corporate Blvd.  
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Eric Chen at 240-276-4173.

Sincerely yours,



Donna-Bea Tillman, Ph.D., M.P.A.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure