



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 2009

Abiomed, Inc.
c/o Mr. Robert T. Kung
22 Cherry Hill Drive
Danvers, MA 01923

Re: K063723
Impella® Recover® LP 2.5 Percutaneous Cardiac Support System
Regulation Number: 21 CFR 870.4360
Regulation Name: Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
Catheter, Cannula and Tubing Vascular, Cardiopulmonary Bypass
Catheter, Intravascular, Diagnostic
Regulatory Class: Class III (three)
Product Code: KFM, DWF, DQO
Dated: May 15, 2008
Received: May 19, 2008

Dear Mr. Kung:

This letter corrects our substantially equivalent letter of May 30, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosur

ABIOMED, Inc.

IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System
Traditional 510(k)

Indications for Use

510(k) Number (if known): K063723

Device Name: IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System

Indications for Use:

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System also provides pressure measurements which are useful in determining intravascular pressure.

Prescription Use X
(Part 21 CFR 801-Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. V. Jones
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K063723

K063723

MAY 30 2008

510(k) Summary (Prepared in accordance with 21 CFR Part 807.92)

a. Submitted

Applicant Name: ABIOMED, Inc.
22 Cherry Hill Drive, Danvers, MA 01923
Contact Person: William J. Bolt
Date Summary Prepared: May 15, 2008

b. Device Information

Trade Name: IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System
Common Name: Percutaneous Cardiac Support System
Classification Name: Pump, Blood, Cardiopulmonary Bypass, non roller type (classified under 870.4360)
Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass (classified under 870.4210)
Diagnostic intravascular catheter (classified under 870.1200)
Product Code: 74KFM, 74DWF, 74DQO

c. Legally Marketed Predicate Devices

- TandemHeart PTVA System – K991783, K052570, K924642, K924643
- Vascular Solutions Langston Dual Lumen Catheter – K050168

d. Device Description:

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System (IMPELLA RECOVER LP 2.5 System) provides circulatory support with the ability to deliver anticoagulant through an infusion system. The System is comprised of: 1) a catheter which contains an integrated pump motor/infusate lumen, integrated intravascular pressure lumen and integral cannula, 2) a controller/console and 3) infusion system designed to work together, and 4) accessories.

e. Intended Use:

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is intended for partial circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. It is also intended to be used to provide partial circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

The IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System also provides pressure measurements which are useful in determining intravascular pressure.

f. Technological Characteristics and Comparison to Predicate Device(s):

The technological characteristics of the IMPELLA RECOVER® LP 2.5 are the same as the TANDEM HEART systems and the Vascular solutions Langston catheter with the exception of the following differences:

- pump location
- certain materials of construction
- pump speed

g. Test Results:

Pre – Clinical:

To validate the device design of the IMPELLA RECOVER® Percutaneous Cardiac Support System, ABIOMED performed the following *in vitro* testing:

With regard to sterilization, packaging, and shelf-life, the IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is sterilized using EtO gas with a SAL of 10^{-6} . The sterilization method/cycle was validated using EN 550 "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization." The EtO sterilization residual values for EO and ECH and are within the allowable limits of ISO 10993-7. The LAL test was used to ensure a pyrogen free determination. The packaging material has been validated to ensure its integrity.

Biocompatibility testing of all patient contacting materials was conducted on the finished sterilized devices in accordance with ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". All testing results are acceptable.

The design and testing validation of the software contained in the IMPELLA MCS was conducted in compliance with the FDA 2005 guidance document entitled "Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

With regard to electromagnetic compatibility and electrical safety, the IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System was tested in accordance with EN 60601 and EN 61000 and their applicable subparts. The testing results demonstrate that the device is in conformance with these FDA recognized standards.

With regard to *In vitro* performance testing, ABIOMED conducted a full range of testing demonstrating that the entire IMPELLA RECOVER® LP 2.5 System operates as intended. All tests were acceptable.

Clinical :

Abiomed provided a detailed analysis based on a clinical data collected from a combination of 109 OUS and 20 US patients used to address patient safety.

h. Conclusion:

The ABIOMED IMPELLA RECOVER® LP 2.5 Percutaneous Cardiac Support System is substantially equivalent to the TandemHeart PTVA System and Control system (K991783), the TandemHeart Transseptal Cannula (K052570), the Medtronic Biomedicus 15F arterial cannula and introducer (K924642, K924643) and the Vascular Solutions Langston Dual Lumen Catheter – K050168