

**510(k) SUMMARY – IMPELLA 5.0**  
**(Prepared in accordance with 21 CFR Part 807.92)**

**Applicant Name:** ABIOMED, Inc.  
22 Cherry Hill Drive  
Danvers, MA 01923

**Contact Person:** Robert Stewart                      **APR 16 2009**

**Date Prepared:** April 15, 2009

**Device Trade Name:** IMPELLA 5.0 Catheters

**Device Common Name:** Extracorporeal Circulatory Support System

**Classification Name:** Non-roller Type Cardiopulmonary Bypass (CPB) Blood Pump

**Predicate Devices:** IMPELLA 2.5 (K063723)  
Estech 21 Fr RAP Cannula (K032632)  
Estech 21 Fr RAP Femoral Cannula (K990573)  
Estech Easy Flow Aortic Cannulae (K060101)  
Calmed 18-24 Fr Aortic Arch Cannulae (K943934)  
Sarn's Delpin Centrifugal Pump (K913176)

**Device Description:** The IMPELLA 5.0 catheter family (IMPELLA 5.0) is an extension of the IMPELLA Percutaneous Cardiac Support product line. The IMPELLA 5.0 is capable of providing up to 5 liters per minute blood flow. The IMPELLA 5.0 are catheter based pumps intended for placement in the left ventricle. There are currently two versions of IMPELLA 5.0 Catheters, one inserted through the femoral artery via cutdown (the IMPELLA 5.0 LP) and the other through the aorta (the IMPELLA 5.0 LD). The only difference between the two versions is the shape of the inflow cannula. The IMPELLA 5.0 catheters provide a means for temporary extracorporeal circulatory support that returns blood to the patient's systemic circulation.  
Each IMPELLA 5.0 Catheter runs as a system comprised of:  
1) a catheter which contains an integrated pump motor/ infusate lumen, integrated intravascular pressure sensor and integral cannula, 2) a controller/console and 3) infusion system designed to work together, and 4) accessories.

**Intended Use:** The IMPELLA 5.0 Catheters are intended for circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. They are also intended to be used to provide circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.  
  
The IMPELLA 5.0 Catheters also provide pressure measurements which are useful in determining intravascular pressure.

**Device Technological Characteristics and Comparison to Predicate Device(s):**

The technological characteristics of the IMPELLA 5.0 are the same as the IMPELLA 2.5, with the exception of a larger pump to permit a higher flow rate and insertion techniques, and minor differences in the impeller blade design and construction material. The IMPELLA 5.0 flow range, up to 5 liters per minute and insertion techniques are equivalent to the listed predicate aortic perfusion cannulae (K032632, K060101, K943934, K990573), when they are used with a cleared CPB system, such as the Sarns Delphin Centrifugal Pump (K913176).

**Performance Data:**

**Pre - Clinical:**

To validate the device design of the IMPELLA 5.0, ABIOMED performed the following in vitro testing:

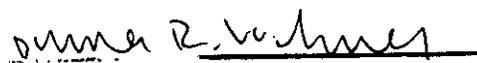
- With regard to sterilization, packaging, and shelf-life, the IMPELLA 5.0 is sterilized using EtO gas with a SAL of  $10^{-6}$ . The sterilization method/cycle was validated using EN 550 "Sterilization of Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization." The EtO sterilization 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-1 0993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". All testing results are acceptable.
- With regard to In Vitro performance testing, ABIOMED conducted a full range of testing demonstrating that the IMPELLA 5.0 Catheters operate as intended. All tests were acceptable.

**Clinical:**

ABIOMED provided a detailed analysis based on a clinical data collected from a combination of 88 OUS and 17-US patients used to address patient safety.

**Conclusion:**

For the purposes of 510(k) clearance, the IMPELLA 5.0 catheters are substantially equivalent to the IMPELLA 2.5 (K063723), Estech 21 Fr RAP Cannula (K032632), Estech 21 Fr RAP Femoral Cannula (K990573), Estech Easy Flow Aortic Cannulae (K060101), the Calmed 24 Fr Aortic Arch Cannulae (K943934), and the Sarns Delphin Centrifugal Pump (K913176).

  
 (Division Sr. Off)  
 Division of Cardiovascular Devices

510(k) Number K083111  
 4/8/2009



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 16 2009

Abiomed, Inc.  
c/o Mr. Robert B. Stewart  
Manager, FDA Programs  
22 Cherry Hill Drive  
Danvers, MA 01923

Re: K083111  
IMPELLA® 5.0 Catheter Family  
Regulation Number: 21 CFR 870.4360  
Regulation Name: Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type  
Regulatory Class: Class III  
Product Code: KFM  
Dated: March 14, 2009  
Received: March 16, 2009

Dear Mr. Stewart:

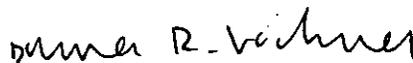
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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.  
Division Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

**Indications for Use**

**510(k) Number (if known):** K083111

**Device Name:** IMPELLA 5.0 Catheters

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The IMPELLA 5.0 Catheters are intended for circulatory support using an extracorporeal bypass control unit, for periods up to 6 hours. They are also intended to be used to provide circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass.

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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)



\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number  K083111