K093801

JUL - 8 2010

IMPELLA CONTROLLER 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807.92.

A. Application Information:

Date Prepared: July 1, 2010

Submitter's Name & Address: ABIOMED, Inc.
22 Cherry Hill Drive
Danvers, MA 01923

Contact Person: Dr. Robert Stewart
Manager, FDA Programs
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B. Device Information:

Trade or Proprietary Name:	IMPELLA Controller
Common or Usual Name:	Non-roller type Cardiopulmonary Blood Pump
Classification Name:	Class III, KFM, 21 CFR - 870.4360
Performance Standard:	Performance standards do not currently exist for these devices. (i.e. none established under section 514 of the F D & C Act)

C. Predicate Device:

The Impella Power Supply, the Impella Mobile Pump Console, and the Braun Vista Basic Purge System, which were cleared for use together as an extracorporeal bypass control unit for the RECOVER LP 2.5 PERCUTANEOUS CARDIAC SUPPORT SYSTEM, K063723.

D. Device Description:

The IMPELLA Controller is a microprocessor-based pump motor driver and purge system. It is designed to operate on AC current (110-240 VAC, 47-63 Hz) or on an internal, rechargeable battery. The IMPELLA Controller generates the signals required to power the drive motor of one of ABIOMED's IMPELLA Percutaneous Support Catheters (the IMPELLA RECOVER LP 2.5 (cleared under K063723), the IMPELLA 5.0 LP and the IMPELLA 5.0 LD (cleared under K083111). The IMPELLA Controller also serves to deliver an infusate of the catheter's drive motor, and to provide useful information regarding the catheter's performance. It is intended to be used by trained healthcare professionals in hospital and medical transport environments. It is lightweight, portable and has an accompanying cart for ease of transport within the hospital.

E. Intended Use:

The IMPELLA Controller is an extracorporeal bypass control unit intended to be used to provide circulatory support for periods up to 6 hours. It is also intended to be used to provide circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass. The Impella Controller is intended to be used by trained healthcare professionals in healthcare facilities and medical transport (i.e. ambulance, helicopter, or fixed-wing aircraft) environments.

The IMPELLA Controller also displays pressure measurement readings, which are useful in determining intravascular pressure.

F. Technological Characteristics:
The IMPELLA Controller employs the same basic, functional scientific technology as its predicate device cleared under K063723.

G. Comparison to Predicate Device:
The IMPELLA Controller has the same intended use as its predicate system, which is made up of a primary, AC powered Power Supply, a Mobile Pump Console, and a Braun VISTA Purge System. The primary function of the IMPELLA Controller remains the same as the predicate system, which is supplying motor power to control and monitor an IMPELLA Percutaneous Support Catheter. The IMPELLA Controller has also been designed to provide ease of patient portability using the same technology as its predicate system. Both the IMPELLA Controller and its predicate system are software driven, microprocessor-based consoles. No modifications to any of the IMPELLA Percutaneous Support Catheters are needed prior to their use with the IMPELLA Controller.

Differences between the IMPELLA Controller and the predicate extracorporeal bypass control unit are the integration of the separate predicate systems (the pump drive hardware, the primary power supply and purge system for the pump motor bearings) into a single control unit, resulting in equivalent performance characteristics to the predicate system. In addition, whereas the predicate console, the Mobile Pump Console utilized a monochromatic display for the display of operational information, the IMPELLA Controller incorporates a Color LCD, for better visibility. The equivalency of the indications for use, the design features and the functional characteristics of the IMPELLA Controller raise no new safety or effectiveness issues.

H. Summary of Performance Data:
The performance characteristics of the IMPELLA Controller were tested in vitro to verify that it met its performance specifications (established by ABIOMED), along with FDA or international standards for software Verification and Validation, and safety testing for EMC, Electrical Safety, and Transport.

The following international standards were met:

- Electromagnetic compatibility testing was in conformance with IEC 60601-1-2, including all pertinent IEC 61000-3-X and IEC 61000-4 –X standards for EMC/EMI along with EN 55011.
- Electrical safety testing was in conformance with IEC 60601-1- Part 1.
- Packaging and shipping testing was in conformance with ISTA 2A and EN 868.
- Altitude and vibration testing during operation was tested per RTCA/DO-160C.

A number of additional standards were applied:

- ISO 1135-4, Transfusion equipment for medical use -- Part 4.
- ISO 8536-4, Infusion equipment for medical use -- Part 4.
- Biocompatibility testing was in conformance with EN ISO 10993-1:2003 and its parts, including EN ISO 10993-7.
- Sterility testing is in conformance with EN ISO 11135.

Software design and testing was in compliance with:

- FDA 2005 document titled "Guidance for Industry and FDA Staff- Guidance for the Content of Pre-market Submissions for Software Contained in Medical Devices".

Internal performance characteristics testing protocols were also used to demonstrate that the IMPELLA Controller performed equivalently to the predicates (given in K063723). The main in vitro systems tests completed were:

- System Durability Testing.
- System Performance Test.
- System Characterization Test.

- System Flow Characterization Test.
- Sensor System Response Test.

Additional specialized performance testing was completed to verify that the IMPELLA Controller met its design specifications.

The performance testing verified that the IMPELLA Controller, met its design specifications, and passed all of the standards testing. Overall, the in vitro performance testing results were equivalent to those demonstrated for the predicate (provided in K063723).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL - 8 2010

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

Re: K093801
IMPELLA® 2.5, 5.0 and 5.0/LD with Mobile Console (IMC)
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-roller type cardiopulmonary bypass blood pump
Regulatory Class: Class III
Product Code: KFM, DWA
Dated: June 18, 2010
Received: June 21, 2010

Dear Dr. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Bachman

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

Enclosure

5.0 INDICATIONS FOR USE

510(k) Number (if known): K093801

Device Name: IMPELLA Controller

Indications for Use:

The IMPELLA Controller is an extracorporeal bypass control unit intended to be used to provide circulatory support for periods up to 6 hours. It is also intended to be used to provide circulatory support (for periods up to 6 hours) during procedures not requiring cardiopulmonary bypass. The Impella Controller is intended to be used by trained healthcare professionals in healthcare facilities and medical transport (i.e. ambulance, helicopter, or fixed-wing aircraft) environments.

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Prescription Use __X__ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (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)

Donna R. Richards
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K093801