APR 27 2011

IMPELLA Controller with Flow Control 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.

K110845

A. Application Information:

Date Prepared: April 27, 2011

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

Contact Person:
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B. Device Information:

Trade or Proprietary Name:	IMPELLA Controller with Flow Control
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 Controller (K093801).

D. Device Description:

The IMPELLA Controller with Flow Control is identical to the IMPELLA Controller in its physical characteristics. The only difference is that an additional operating mode, Flow Control Mode, has been implemented via a software modification. Both the IMPELLA Controller and the IMPELLA Controller with Flow Control are identical microprocessor-based pump motor drivers incorporating an infusion system. They both are intended to be used by trained healthcare professionals in hospital and medical transport environments.

E. Intended Use:

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

F. Technological Characteristics:

The IMPELLA Controller with Flow Control employs identical functional scientific technology as its predicate device cleared under K093801.

G. Comparison to Predicate Device:
The IMPELLA Controller with Flow Control has the same intended use as its predicate system, the IMPELLA Controller. The primary function of the IMPELLA Controller with Flow Control is identical to that of the predicate system, which is supplying motor power and infusate to control and monitor an IMPELLA Percutaneous Support Catheter. Both the IMPELLA Controller with Flow Control and its predicate system are software driven, microprocessor-based consoles. It has a hardware configuration identical to the IMPELLA Controller.

The only difference between the IMPELLA Controller with Flow Control and the predicate IMPELLA Controller is a modification in the internal software to allow a Flow Control Mode of operation, which permits the User to set the circulatory support level (i.e. outflow from the non-roller pump) of the IMPELLA Percutaneous Support Catheters. The IMPELLA Controller, on the other hand, uses a Speed (called "Performance level") Control Mode (P1 to P9) to control the RPM of the miniature centrifugal pump motors in the IMPELLA Percutaneous Catheters. The Speed Control Mode is still available in the IMPELLA Controller with Flow Control. The equivalency of the indications for use, the design features and the functional characteristics of the IMPELLA Controller with Flow Control raise no new safety or effectiveness issues.

H. Summary of Performance Data:
As with the predicate IMPELLA Controller (cleared under K093801):

International standards were met for the IMPELLA Controller with Flow Control:

- 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.

Software design & testing for the IMPELLA Controller with Flow Control complied 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".

Performance characteristics of the IMPELLA Controller with Flow Control were tested in vitro to verify that the new Flow Control Mode met its specifications. The main in vitro systems tests completed were:

- System Durability Testing.
- System Characterization Test.
- System Flow Characterization Test.

Additional specialized performance testing was completed to verify that the 2 control modes are substantially equivalent. This testing showed that the Flow Control Algorithm behaves as designed, and that the 2 control modes are equivalent for use with the IMPELLA pump catheters.

The results of the bench testing demonstrated that the IMPELLA Controller with Flow Control did not raise new issues with safety or effectiveness.

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

ABIOMED, Inc.
c/o Dr. Robert Stewart
22 Cherry Hill Drive
Danvers, MA 01923

APR 27 2011

Re: K110845
Trade/Device Name: IMPELLA Controller with Flow Control
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-roller type cardiopulmonary bypass blood pump
Regulatory Class: III
Product Code: KFM, DWA
Dated: March 25, 2011
Received: March 28, 2011

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,

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

Enclosure

6.0 INDICATIONS FOR USE

510(k) Number (if known): K110845

Device Name: IMPELLA Controller with Flow Control

Indications for Use:

The IMPELLA Controller with Flow Control 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 with Flow Control 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)

for (Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110845