DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

September 20, 2017

Abiomed, Inc.
Mr. William Bolt
Senior Vice President, Global Quality, Regulatory and Clinical Operations
22 Cherry Hill Drive
Danvers, Massachusetts 01923

Re: P170011
Trade/Device Name: Impella RP® System
Filed: March 30, 2017
Amended: June 1 and June 2, 2017
Product Code: PYX

Dear Mr. Bolt:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval (PMA) application for the Impella RP® System. This device is indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area ≥1.5 m^2, who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant, or open-heart surgery. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). The device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device. FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for the Impella RP Catheter and the Impella Purge Cassette has been established and approved at 2 years.

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. Two copies of this report, identified as "Annual Report" and

bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84. This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final UDI rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below. Separate PAS Progress Reports must be submitted for each study according to the schedules specified below. Two (2) copies of each report, identified as an "OSB Lead PMA Post-Approval Study Report" in accordance with how the study is identified below and bearing the applicable PMA reference number, should be submitted to the address below.

1. **OSB Lead PMA Post-Approval Study** – ***Impella RP*** – ***Real-World Evidence Evaluation and Periodic Reporting***: You are required to provide post-approval safety and effectiveness data to FDA on the Impella RP System per the PAS protocol (version 1.0) dated August 14, 2017. Data will be captured in the cVAD Registry through 1 year post-Impella RP explant.

   You must provide analysis results on 60 consecutively treated patients (age ≥ 18 years old). The patients will be treated and followed according to standard of care and institution guidelines. Post-discharge data will be collected prospectively through telephone contact and review of existing medical records at 30 days, 90 days and 1 year.

   You will perform analyses and provide results on the following outcomes: (a) survival rate at 30 days post device explant or hospital discharge (whichever is longer), or at induction of anesthesia to a longer term therapy, which includes heart transplant or implantation of a surgical right ventricular assist device (RVAD); (b) bleeding, hemolysis and pulmonary embolism at 30 days or discharge (whichever is longer); and (c) device malfunction, central venous pressure, cardiac index, and left ventricular assist device (LVAD) flow.

The study results will be presented descriptively as means and standard deviations and compared against those reported in the PMA application where applicable.

You are required to provide reports to FDA every 6 months for the first two years after PMA approval, and annually thereafter.

2. **OSB Lead PMA Post-Approval Study** – ***Impella RP Pediatric*** – ***Real-World Evidence Evaluation and Periodic Reporting***: You are required to provide post-approval safety and effectiveness data to FDA on the Impella RP System for the pediatric patients per the analysis plan (version 1.0) dated August 17, 2017. This study is a continuation of the "Impella RP Pediatric Study" ordered as a condition of approval for the Impella RP HDE H140001. Data from the pediatric patients will continue to be captured in the cVAD Registry at a minimum of 5 sites.

   You must provide analysis results on 15 consecutively treated pediatric patients under 18 years of age or all pediatric patients under 18 years of age treated over a 5-year period (whichever comes first). The patients will be treated and followed according to standard of care and institution guidelines. Post-discharge data will be collected retrospectively at 30 days and 180 days.

   You will perform analyses and provide results on the following outcomes: (a) survival rate at 30 days post device explant or hospital discharge (whichever is longer), or at induction of anesthesia to a longer term therapy, which includes heart transplant or implantation of a surgical right ventricular assist device (RVAD); (b) bleeding, hemolysis and pulmonary embolism at 30 days or discharge (whichever is longer); (c) device malfunction, central venous pressure, cardiac index, and left ventricular assist device (LVAD) flow; and (d) survival rate at 180 days.

   The study results will be presented descriptively as means and standard deviations and compared against those reported in the PMA application where applicable.

   You are required to provide reports to FDA every 6 months.

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA.

Be advised that protocol information, interim and final results will be published on the Post Approval Study Webpage http://www.fda.gov/devicepostapproval.

In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by PMA Order"

(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070974.htm).

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089274.htm.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

In accordance with the recall requirements specified in 21 CFR 806.10, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at http://www.fda.gov/Safety/Recalls/IndustryGuidance/default.htm.

CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, 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/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 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 submitting a petition for review under

section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.

Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

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 final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final 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 6 copies, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

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If you have any questions concerning this approval order, please contact Changfu Wu, Ph.D., at 301-796-6086 or Changfu.Wu@fda.hhs.gov.

Sincerely,

Nicole G. Ibrahim -S

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