December 12, 2020

Abiomed Inc.
K. Ryder
Senior Director, Global Regulatory Operations
22 Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K202330
Trade/Device Name: Impella XR Sheath Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 14, 2020
Received: August 17, 2020

Dear K. Ryder:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Finn Donaldson
Assistant Director
DHT2C: Division of Coronary and Peripheral Interventional Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202330

Device Name
Impella XR Sheath Set

Indications for Use *(Describe)*
The Impella XR Sheath Set is intended for use for the percutaneous introduction of the Impella 2.5 Catheter and ancillary devices.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Impella XR Sheath Set- K202330

510(k) Summary

This 510(k) summary 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:	November 23, 2020
Submitter's Name & Address:	ABIOMED, Inc. 22 Cherry Hill Drive Danvers, MA 01923
Contact Person:	J. Kenneth Ryder Senior Director, Global Regulatory Affairs Ph: 978-646-1707 E-mail: kryder@abiomed.com

B. Device Information:

Trade Name:	Impella XR Sheath Set
Common or Usual Name:	Introducer, Catheter
FDA Classification:	Class II, DYB, 21 CFR- 870.1340
Regulation Description:	Catheter Introducer

C. Predicate Device:

Boston Scientific 14 Fr iSLEEVE Introducer Set, which is cleared under K180785, and 10 Fr Arrow Percutaneous Sheath Introducer, which is cleared under K780532.

The predicate devices have not been subjected to any design-related recall.

D. Device Description:

The Impella XR Sheath Set is a sterile, single-use, prescription device. The Impella XR Sheath Set consists of an introducer sheath (Impella XR Introducer Sheath) and a tapered sheath dilator (Impella XR Dilator) which is compatible with a 0.035" guidewire. The Impella XR Sheath Set is kitted with a 0.035" access guidewire and a supplemental dilator in the Impella XR Sheath Kit for convenience to help facilitate insertion.

The Impella XR Introducer Sheath consists of a sheath hub with a three-way stop cock and flush port at its proximal end and an expandable sheath body at its distal end. The sheath hub features an introducer cap, hemostasis valve, side-port with three-way stop cock and flush port, a butterfly (suture pad), and connects with the dilator hub. The sheath body has an insertion profile of 10 Fr and expands after removal of the dilator to allow the insertion of the Impella 2.5 catheter. The sheath body also features a hydrophobic coating to aid in the insertion of the introducer sheath.

The Impella XR Dilator consists of a dilator body, a tapered tip at the distal end, and a hub at the proximal end, which connects with the sheath hub.

E. Intended Use/Indications for Use:

INTENDED USE:

The Impella XR Sheath Set is intended to facilitate femoral access to the vascular system.

INDICATIONS FOR USE:

The Impella XR Sheath Set is intended for use for the percutaneous introduction of the Impella 2.5 Catheter and ancillary devices.

F. Technological Characteristics Comparison of Subject and Predicate Devices:

The subject device, Impella XR Sheath Set, is substantially equivalent to the predicate device, 14 Fr iSLEEVE Introducer Set, in intended use, indications for use, anatomical access site, overall system components (including the expandable functionality), operating principle, general use steps, radiopacity, sterilization, and guidewire compatibility. The reference device, the 10 Fr Super Arrow-Flex Sheath, has similar length and insertion profile to the subject device.

Manufacturer	**Boston Scientific (Predicate Device)**	**Teleflex Super Arrow-Flex (Reference Device)**	**Abiomed (New Device)**
Model Name	14 Fr iSLEEVE Introducer Set	10 Fr Super Arrow-Flex Sheath	10 Fr Impella XR Sheath Set
510k Number	K180785	K780532	-
Intended Use	The iSLEEVE Introducer Set is intended to facilitate femoral access to the vascular system.	The Super Arrow-Flex Sheath is intended to facilitate access to the vascular system.	The Impella XR Sheath Set is intended to facilitate femoral access to the vascular system.
Indications for Use	The 14F iSLEEVE Introducer Set is intended to facilitate femoral access to the vascular system for introduction and removal of the ACURATE TF Valve System and ancillary devices. The iSLEEVE Introducer Set is suitable for use in vessels ≥ 5.5 mm diameter.	The Super Arrow-Flex Sheath is intended for use in the hospital catheterization laboratory for the percutaneous introduction of various devices into veins and/or arteries in a variety of diagnostic and therapeutic procedures.	The Impella XR Sheath Set is intended for use for the percutaneous introduction of the Impella 2.5 Catheter and ancillary devices.
Useable Length	32 cm	11 cm	15 cm

Manufacturer	**Boston Scientific (Predicate Device)**	**Teleflex Super Arrow-Flex (Reference Device)**	**Abiomed (New Device)**
Insertion Profile	14 Fr	10 Fr	10 Fr
Operating Principle and General Use Steps	Operated manually or by a manual process. Standard techniques for placement of vascular access sheaths	Operated manually or by a manual process. Standard techniques for placement of vascular access sheaths	Operated manually or by a manual process. Standard techniques for placement of vascular access sheaths
Radiopacity	Radiopaque marker at distal tip of sheath	Radiopaque marker at distal tip of sheath	Radiopaque sheath (metal braid)
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Guidewire	0.035" (or smaller) compatible guidewire	0.035" (or smaller) compatible guidewire	0.035" (or smaller) compatible guidewire

G. Performance Testing:

The following performance testing was conducted on the Impella XR Sheath Set.

Bench Testing:

- Visual Inspection and Dimensional Verification
- Sheath System Verification
- Packaging Validation
- Sterilization Validation
- Shelf Life
- Biocompatibility

Pre-clinical Testing:

A GLP animal study was executed to evaluate the performance of the Impella XR Sheath Set using an acute animal model in a simulated use environment.

H. Conclusions

Performance testing (bench and preclinical) was completed and showed that the subject device, Impella XR Sheath Set, met the acceptance criteria and demonstrated substantial equivalence for its intended use. No new safety or performance issues were identified during the testing; therefore, the subject device may be considered substantially equivalent to the predicate devices.