October 13, 2022

Abiomed Inc.
Ken Ryder
Sr. Director, Regulatory Affairs
22 Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K222113
Trade/Device Name: Abiomed 14Fr Low Profile Introducer Set
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 15, 2022
Received: July 18, 2022

Dear Ken 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,

Nicole Gillette
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222113

Device Name
Abiomed 14 Fr Low Profile Introducer Set

Indications for Use *(Describe)*
The 14 Fr Low Profile Introducer Set is intended to facilitate access to the vascular system for the introduction and removal of the Impella CP 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Abiomed 14Fr Low Profile Introducer Set 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 15, 2022
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 or Proprietary Name:	Abiomed 14Fr Low Profile Introducer Set
Common or Usual Name:	Introducer, Catheter
FDA Classification:	Class II, DYB, 21 CFR 870.1340
Regulation Description:	Catheter Introducer

C. Predicate Device:

The primary predicate device was the Gore DrySeal Flex Introducer Sheath, which is cleared under K160254. The reference device was the Teleflex 10 Fr Arrow Sheath, which is cleared under K780532.

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

D. Device Description:

The Abiomed 14Fr Low Profile Introducer Set is a sterile, single-use, prescription device. The 14Fr Low Profile Introducer Set consists of an introducer sheath and a tapered sheath dilator which is compatible with an 0.035" guidewire. The 14Fr Low Profile Introducer Set is kitted with an 0.035" access guidewire, supplemental dilators and a luer adapter for convenience to help facilitate insertion.

The 14Fr Low Profile Introducer Sheath consists of a sheath hub with three-way stopcock and flush port at its proximal end and a sheath body at its distal end. The sheath hub features an introducer cap, hemostasis valve, side-port with three-way stopcock and flush port, a butterfly (suture pad), and connects to the dilator hub. The coil reinforced polymer sheath body has an insertion profile of 14 Fr to allow the insertion and removal of the Impella CP Catheter and ancillary

devices. The 14 Fr Low Profile 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. Additionally, the 14Fr dilator has a hydrophilic coating to aid in insertion of the device into the vasculature.

E. Indications for Use:

INDICATIONS FOR USE:

The 14Fr Low Profile Introducer Set is intended to facilitate access to the vascular system for the introduction and removal of the Impella CP Catheter and ancillary devices.

F. Technological Characteristics Comparison of Subject and Predicate and Reference Devices:

The subject device, 14 Fr Low Profile Sheath, is identical to the predicate and reference devices in Intended Use, general system components, sterilization, guidewire compatibility, insertion profile, and general mechanism of action. Differences between the subject device and the predicate and reference devices were all determined to be minor, have no adverse impact on safety or effectiveness, and raise no different questions of safety or effectiveness compared to the predicate devices. These minor differences include Indications for Use, length, sheath design, hub design, dilator design, coating location, and method for achieving radiopacity.

Property	Primary Predicate	Reference Device	Subject Device
Manufacturer/ Model Name/ 510k Clearance	**Gore DrySeal Flex Introducer Sheath/ K160254**	**Teleflex 10Fr Arrow Sheath/ K780532**	**Abiomed 14 Fr Low Profile Introducer Set/ this submission**
Intended Use	The GORE DrySeal Sheath is intended to facilitate access into the vascular system.	The Arrow Sheath is intended to facilitate access into the vascular system.	The 14Fr Low Profile Introducer Set is intended to facilitate access into the vascular system.
Indications for Use	The GORE DrySeal Sheath is intended to be inserted in the vasculature to provide a conduit for the insertion of endovascular devices while minimizing blood loss associated with such insertions.	The Arrow 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 14Fr Low Profile Introducer Set is intended to facilitate access to the vascular system for the introduction and removal of the Impella CP Catheter and ancillary devices
General System Components	A sheath consisting of hub with hemostasis valve, extension tube with stopcock, and a dilator with luer.		
Sterilization	Ethylene Oxide		
Guidewire	0.035” (or smaller) compatible guidewire		

Property	Primary Predicate	Reference Device	Subject Device
Manufacturer/ Model Name/ 510k Clearance	**Gore DrySeal Flex Introducer Sheath/ K160254**	**Teleflex 10Fr Arrow Sheath/ K780532**	**Abiomed 14 Fr Low Profile Introducer Set/ this submission**
Length	32-64 cm	11 cm	13, 25 cm
Insertion Profile	14 Fr	10 Fr	14 Fr
Sheath	Stainless steel reinforced hydrophilic coated Pebax tube with PTFE liner	Rigid composite tube (polymer coated metal coil)	Stainless steel reinforced Pebax tube
Hub	Cap (polymer) w/ hemostasis valve (polymer), extension tube (polymer) w/ stopcock (polymer), suture eyelet	Cap (polymer) w/ hemostasis valve (polymer), extension tube (polymer) w/ stopcock (polymer)	Cap (polymer) w/ hemostasis valve (polymer),extension tube (polymer) w/ stopcock (polymer), suture pad (polymer)
Dilator	Tapered dilator (polymer) w/ Luer (polymer)	Dilator (polymer) w/ Luer (polymer)	Tapered dilator (polymer) w/ Luer (polymer) with hydrophilic coating at dilator tip
Coating	Hydrophilic coating	Hydrophilic coating	Hydrophilic coating at dilator tip
Mechanism of Action, General	Inserted manually using standard techniques. Sheath left indwelling (in vessel) after insertion and dilator removal.		
Radiopacity	Radiopaque (sheath has marker at distal tip)		Radiopaque (sheath has internal metal coil)

G. Performance Testing:

The following performance testing was conducted on the Abiomed 14Fr Low Profile Introducer Set.

Bench Testing:

- Visual Inspection and Dimensional Verification
- Sheath System Verification
- Simulated Use Testing
- Packaging Validation
- Biocompatibility Testing
- Sterilization Assessment
- Leak Testing
- Mechanical Testing
- Coating Integrity
- Particulate
- Radiopacity

H. Conclusions:

Performance testing (bench) was completed and showed that the subject device, Abiomed 14Fr Low Profile Introducer Set, met the acceptance criteria and demonstrated substantial equivalence for its intended use. Biocompatibility safety testing conducted in accordance with ISO 10993-1 demonstrates that the device is safe for its patient contact and duration. No clinical data were required to demonstrate substantial equivalence. No new safety or performance issues were identified during the testing; therefore, the subject device may be considered substantially equivalent to the predicate and reference device.