October 8, 2025

Abiomed Inc.
Anshul Shah
Director, Regulatory Affairs
22 Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K252766
Trade/Device Name: 14Fr Low Profile Introducer Kit
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter introducer
Regulatory Class: Class II
Product Code: DYB
Dated: August 29, 2025
Received: August 29, 2025

Dear Anshul Shah:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Meaghan Erlewein -S

For 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K252766

Device Name

Abiomed 14Fr Low Profile Introducer Kit

Indications for Use *(Describe)*

The Abiomed 14Fr Low Profile Introducer Kit 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Abiomed 14Fr Low Profile Introducer Kit 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:	August 22, 2025
Submitter's Name & Address:	ABIOMED, Inc. 22 Cherry Hill Drive Danvers, MA 01923
Contact Person:	Anshul Shah Director, Regulatory Affairs Ph: 323-541-5318 E-mail: anshah@abiomed.com

B. Device Information:

Trade or Proprietary Name:	Abiomed 14Fr Low Profile Introducer Kit
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 Abiomed 14Fr Low Introducer Kit, which is cleared under K241708.

D. Device Description:

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

The Abiomed 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 14Fr to allow the insertion and removal of the Impella CP Catheter and ancillary devices.

The Abiomed 14Fr 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 Abiomed 14Fr Low Profile Introducer Kit 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 Devices:

The subject device, Abiomed 14Fr Low Profile Introducer Kit, is identical to the predicate device in its intended use, indications for use, design, general system components, sterilization, guidewire compatibility, insertion profile, and general mechanism of action. As there are no differences between the subject and predicate devices, there is no impact to device safety or effectiveness.

Property	**Primary Predicate**	**Subject Device**
Manufacturer/ Model Name/ 510k Clearance	**Abiomed 14Fr Low Profile Introducer Kit / K241708**	**Abiomed 14Fr Low Profile Introducer Kit/ this submission**
Intended Use	The Abiomed 14Fr Low Profile Introducer Set is intended to facilitate access into the vascular system.	The Abiomed 14Fr Low Profile Introducer Kit is intended to facilitate access into the vascular system.
Indications for Use	The Abiomed 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.	The Abiomed 14Fr Low Profile Introducer Kit 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, sidearm with stopcock, and a dilator with luer.	
Sterilization	Ethylene Oxide	
Guidewire	0.035” (or smaller) compatible guidewire	
Length	13, 25 cm	13, 25 cm
Insertion Profile	14Fr	14Fr
Sheath	Stainless steel reinforced Pebax tube	Stainless steel reinforced Pebax tube
Hub	Cap (polymer) w/ hemostasis valve (polymer), sidearm (polymer) w/ stopcock (polymer), suture pad (polymer)	Cap (polymer) w/ hemostasis valve (polymer), sidearm (polymer) w/ stopcock (polymer), suture pad (polymer)
Dilator	Tapered dilator (polymer) w/ Luer (polymer) with hydrophilic coating at dilator tip	Tapered dilator (polymer) w/ Luer (polymer) with hydrophilic coating at dilator tip

Property	Primary Predicate	Subject Device
Manufacturer/ Model Name/ 510k Clearance	**Abiomed 14Fr Low Profile Introducer Kit / K241708**	**Abiomed 14Fr Low Profile Introducer Kit/ this submission**
Coating	Hydrophilic coating at dilator tip	Hydrophilic coating at dilator tip
Mechanism of Action, General	Inserted manually using standard techniques. Sheath left indwelling (in vessel) after insertion and dilator removal.	Inserted manually using standard techniques. Sheath left indwelling (in vessel) after insertion and dilator removal.
Radiopacity	Radiopaque (sheath has internal metal coil)	Radiopaque (sheath has internal metal coil)

G. Performance Testing:

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

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:

This submission was limited to labeling changes. The previous performance testing (bench) that was completed for the Abiomed 14Fr Low Profile Introducer Kit (K241708) is applicable to the subject device as there have been no changes to the design, general system components, sterilization, guidewire compatibility, insertion profile, and general mechanism of action. All performance data met predetermined 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 was 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 device.