June 15, 2020

Abiomed Inc.
Sandy Fowler
Regulatory Affairs Specialist
22 Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K201116
Trade/Device Name: Abiomed 23 Fr Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: April 24, 2020
Received: April 27, 2020

Dear Sandy Fowler:

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,

Hetal Odobasic
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
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)*
K201116

Device Name
Abiomed 23 Fr Sheath

Indications for Use *(Describe)*
The Abiomed 23 Fr Sheath is intended for introduction of pacing leads or catheters.

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 23 Fr Sheath 510(k) Summary

This summary of 510(k) 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:	April 24th, 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 or Proprietary Name:	Abiomed 23 Fr Sheath
Common or Usual Name:	Introducer, Catheter
FDA Classification:	Class II, DYB, 21 CFR- 870.1340
Regulation Description:	Catheter Introducer
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:

Oscor Adelante-S Introducer Series, K122084

D. Device Description:

The Abiomed 23 Fr Sheath is packaged as a sterile kit, which includes an introducer sheath (consisting of sheath with sideport tubing, stopcock and hemostasis valve assembly), and dilators, and a guidewire. It is identical to the commercially available predicate device, the Oscor 23 Fr Adelante-S2 Introducers, K122084.

E. Intended Use:

The Abiomed 23 Fr Sheath is intended for introduction of pacing leads and catheters into the body.

F. Comparison of Required Technological Characteristics:

All technological characteristics of the Abiomed 23 Fr Sheath are identical to its commercially available predicate, including its design, packaging, manufacturing, sterilization, and labeling.

G. Comparison to Predicate Device:

The Abiomed 23 Fr Sheath is identical to its commercially available predicate device.

H. Qualification Testing:

Since the Abiomed 23 Fr Sheath is identical to its commercially available predicate device, no additional qualification testing was required for the substantial equivalence determination.