March 1, 2023

Abbott Medical
Chidalu Mozie
Regulatory Affairs Specialist
15900 Valley View Court
Sylmar, California 91342

Re: K230283
Trade/Device Name: Peel-Away Introducer (405104, 405108, 405112, 405116, 405118, 405119, 405120, 405122, 405124, 405128, 405129, 405136, 405144, 405145, 405146, 405147, 405149, 405153, 405154, 405254, 405269, 405270, 405404, 405408, 405412, 405416, 405418, 405420, 405422, 405424, 405428)
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 31, 2023
Received: February 1, 2023

Dear Chidalu Mozie:

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 B. Patel -S

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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K230283

Device Name

Peel-Away Introducer (405104, 405108, 405112, 405116, 405118, 405119, 405120, 405122, 405124, 405128, 405129, 405136, 405144, 405145, 405146, 405147, 405149, 405153, 405154, 405254, 405269,
405270, 405404, 405408, 405412, 405416, 405418, 405420, 405422, 405424, 405428)

Indications for Use *(Describe)*

The Peel-Away Introducers are intended to provide a transvenous conduit for the introduction of cardiac leads and catheters into the venous vascular system.

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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510(k) Summary

Prepared on: 2023-01-31

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Abbott Medical
Applicant Address	15900 Valley View Court Sylmar CA 91342 United States
Applicant Contact Telephone	8172333219
Applicant Contact	Ms. Chidalu Mozie
Applicant Contact Email	chidalu.mozie@abbott.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Peel-Away Introducer (405104, 405108, 405112, 405116, 405118, 405119, 405120, 405122, 405124, 405128, 405129, 405136, 405144, 405145, 405146, 405147, 405149, 405153, 405154, 405254, 405269, 405270, 405404, 405408, 405412, 405416, 405418, 405420, 405422, 405424, 405428)
Common Name	Catheter introducer
Classification Name	Introducer, Catheter
Regulation Number	870.1340
Product Code	DYB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K013029	Seal Away CS Introducer Kit	DYB

Device Description Summary

21 CFR 807.92(a)(4)

The Peel-Away Introducers provide cardiovascular leads and catheters access to the venous vascular system for cardiac surgery procedures. Peel-Away Introducer sheaths have a straight shaft. The sheath is the outer component and the dilator fits inside the sheath with the distal end protruding out. A needle, which is connected to the syringe, is used to gain access to the vessel. After blood flow is established, the syringe is removed and a guidewire is inserted through the needle and advanced into the vessel. The assembled sheath/dilator combination is advanced over the guidewire into the vessel. At the proximal end of the sheath is a t-handle hub, which is designed to split and facilitate the peeling action of the scored sheath tubing. The sheath tubing is designed to peel continuously and symmetrically for safe removal of the introducer while maintaining venous access.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Peel-Away Introducers are intended to provide a transvenous conduit for the introduction of cardiac leads and catheters into the venous vascular system.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Peel Away Introducer kits, with the new replacement syringe accessory, have the following similarities to the predicate devices (Seal Away introducer kits) which previously received 510(k) clearance (K013029):
- have the same underlying intended use,
- have the same fundamental scientific technology,
- are sterilized using the same processes.

In summary, the Peel Away Introducer products described in this submission are substantially equivalent to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The new syringe accessory has the same technological characteristics as the syringe accessory in the currently marketed Peel-Away Introducer kits, with only minimal changes to the syringe material to ensure compliance with current regulatory requirements and standards.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The addition of the Exel syringe and modification of the packaging tray necessitated packaging, biocompatibility, and sterilization testing. Completion of all verification and validation activities demonstrated that the syringe meets its predetermined design and performance specifications, and that the peel-away introducer with the new syringe accessory is substantially equivalent to the predicate device.