July 27, 2021

Abbott Medical
Bijal Patel-Jain
Sr. Manager, Regulatory Affairs
15900 Valley View Court
Sylmar, CA 91342

Re: K211989
Trade/Device Name: Aveir Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 25, 2021
Received: June 28, 2021

Dear Bijal Patel-Jain:

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,

for

Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K211989

Device Name
Aveir Introducer

Indications for Use *(Describe)*
The Aveir™ Introducer is intended to provide a conduit into the venous system for insertion of diagnostic and other interventional 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.

Aveir™ Introducer (LSN25301, LSN25501), Special 510(K) Pre-Market Notification

K211989

Submitter

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Date Prepared: June 25, 2021

Contact Person

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Device

Name of Device:	Aveir™ Introducer
Model Number:	LSN25301 (30cm) and LSN25501 (50cm)
Common or Usual Name:	Introducer, Catheter
Classification Name:	Catheter Introducer (21 CFR 870.1340)
Regulatory Class:	II
Code:	DYB

Pediatric Use

The Aveir™ Introducer has not been specifically tested for use in pediatric patients.

Predicate Device

The modified Aveir™ Introducer is substantially equivalent in intended use and method of operation to the predicate devices manufactured by Abbott:

- Nanostim™ Introducer Kit 30 cm, model S1S18F (K160716)
- Nanostim™ Introducer Kit 50 cm, model LSN18501 (K161102)

Device Description

The Aveir™ Introducer is designed to perform as a guiding sheath for introduction of diagnostic or interventional devices. It is intended to provide a conduit into the venous system for insertion of diagnostic or interventional devices. The Aveir™ Introducer has a 25 French (Fr) inner diameter and comes in two lengths – Model LSN25301, 30 cm, and Model LSN25501, 50 cm. The only difference between the two models is the length.

The Aveir™ Introducer comprises the following two components:

1) Introducer sheath with a flush port and a three-way stopcock
   The introducer sheath is coated with a hydrophilic coating and is fitted with a suture loop, a sideport with a three-way stopcock, and a hemostasis valve, which minimizes air introduced and maintains hemostasis during insertion and/or exchange. The sheath contains a radiopaque tip marker incorporated within the sheath material to identify the location of the distal tip sheath. The dilator contains a locking mechanism that locks the dilator into the introducer sheath.
2) Dilator
   The dilator contains a locking mechanism that locks the dilator into the introducer sheath.

The introducer sheath and dilator are supplied sterile (via ethylene oxide) in one package and are intended for single procedure.

Indications for Use/ Intended Use

The Aveir™ Introducer is intended to provide a conduit into the venous system for insertion of diagnostic and other interventional devices.

Comparison of Technological Characteristics with Predicate Device

The subject and predicate devices have the same intended use, and similar technological characteristics and performance. Both the subject device and predicate devices are intended to provide a conduit into the venous system for insertion of diagnostic and other interventional devices.

At a high-level, the subject and predicate devices are based on the following technological elements that are the same:

- Same intended use statement
- Radiopaque filler and radiopaque marker band in the distal tip to view its location during a procedure
- Length options: 30 cm and 50 cm
- A hermetic seal included in the Introducer's hub/seal to provide hemostasis
- Smooth introducer tip transition and retention when the introducer sheath and dilator are connected, preventing movement of the introducer beyond the dilator tip transition, thus mitigating vessel trauma during insertion.
- The extrusions of the Introducer sheath and dilator are the same.

The following technological differences exist between the subject and predicate devices:

- a 25 French (Fr) inner diameter to enable the Aveir™ leadless pacemaker to remain fully covered during venous access to simplify the procedure and reduce risk of procedural error
- a twist locking mechanism to the dilator rather than a snap fit
- a hydrophilic coating to the sheath for ease of insertion.

These differences were evaluated through performance testing, which demonstrated that the Aveir™ Introducer performs in a substantially equivalent manner to currently marketed predicate devices.

Performance Data

The Aveir™ Introducer is substantially equivalent to the predicate devices based on comparisons of the intended use, device functionality, and technological characteristics. The following performance testing was conducted to demonstrate that the device meets its design specifications and is substantially equivalent to the predicate devices:

Biocompatibility Testing

The biocompatibility evaluation for the Aveir™ Introducer was conducted in accordance with ISO 10993-1 for biological evaluation and FDA Guidance *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* issued September 4, 2020. For biological testing in animal models, testing was conducted in accordance with FDA Good Laboratory Practice (GLP) Regulations 21 CFR 58.

The Aveir™ Introducer is considered an external communicating device in contact with circulating blood for less than 24 hours per ISO 10993-1 guidelines.

The testing included the following:

- Cytotoxicity
- Sensitization
- Irritation (Intracutaneous Reactivity)
- Acute Systemic Toxicity
- Materials Mediated Pyrogenicity
- Hemocompatibility
    - Direct contact and extract hemolysis
    - Complement activation assay – SC5b-9
    - In-vivo thrombogenicity – Anticoagulated Venous Implant (AVI) and Non-Anticoagulated Venous Implant (NAVI)
- Particulate Matter per USP <788>

Bench Testing

- Design Verification
    - Physical and Dimensional Characteristics
    - Functional Characteristics
    - Hydrophilic Coating Lubricity and Durability
- Packaging and Shelf Life Testing
    - Nominal T=0
    - Accelerated Aging 12-month

Animal Testing

Usability validation testing including the Aveir™ Introducer was conducted through an acute GLP study. This GLP study were performed as defined by 21 CFR Part 58 "Good Laboratory Practice for Nonclinical Laboratory Studies" at a USDA registered facility, which is also accredited by AAALAC International.

The usability study was conducted for the intended use workflows where the Introducer is utilized to implant or retrieve a leadless pacemaker via femoral vein.

Based on the results of usability validation testing, the Aveir™ Introducer possesses acceptable usability and acceptable residual usability risk based on the observed difficulties and use errors of

the participants. All acceptance criteria were met under the conditions of the study. There were no observed use errors that could result in serious patient harm.

Conclusions

The resulting evidence obtained from the design verification and validation testing demonstrated that the subject device is substantially equivalent to the predicate devices.