April 1, 2022

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

Re: K213494
Trade/Device Name: Aveir Retrieval Catheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy Catheter
Regulatory Class: Class II
Product Code: MMX
Dated: March 31, 2022
Received: April 1, 2022

Dear Bijal 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,

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.

510(k) Number *(if known)*

Device Name
Aveir™ Retrieval Catheter

Indications for Use *(Describe)*

The Aveir Retrieval Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to retrieve and manipulate an Abbott Medical leadless pacemaker (LP). Retrieval and manipulation includes removing the LP from the heart or peripheral vasculature.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements set forth in 21 CFR 807.92.

510(k) Number K213494

I. SUBMITTER

Owner Name: Abbott Medical
Address: 15900 Valley View Court
Sylmar, CA 91342 USA
Phone: (818) 362-6822

Contact Person Bijal Patel-Jain
Senior Manager of Regulatory Affairs

Date Prepared: March 31, 2022

II. DEVICE

Name of Device	Aveir™ Retrieval Catheter
Model Number (s)	LSCR111
Common or Usual Name	Retrieval, Catheter, Snare System
Classification Name	Catheter Retrieval (21 CFR 870.5150)
Regulatory Class	Class II
Product Code	MMX

III. PEDIATRIC USE

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

IV. PREDICATE DEVICE

The Aveir™ Retrieval Catheter is substantially equivalent in intended use and method of operation to the predicate devices listed below:

- 510(k) K092343: Merit Medical, EN Snare® Endovascular Snare System
- 510(k) K122088: Merit Medical, One Snare® Endovascular Snare System
- 510(k) K133681: Volcano Corporation, Crux® Snare Filter Retrieval Set

V. DEVICE DESCRIPTION

The Aveir™ Retrieval Catheter, model LSCR111 comprised of a valve bypass tool, a steerable/deflectable catheter, an integrated guiding catheter with a protective sleeve, and a tri-loop snare, assembled into a single catheter. The tri-loop snare, secured to a shaft, is used to grasp the docking feature on the proximal end of an Abbott Medical Leadless Pacemaker (LP), mate the LP to the Retrieval Catheter, unscrew the LP and retrieve the LP, thereby removing the LP from the patient's heart or peripheral vasculature. The Retrieval Catheter is supplied in a sterile pouch (sterilized via ethylene oxide), is intended for single-use only, and may not be re-sterilized.

This device is an accessory designed to be used with both the Aveir Leadless System and the previous Nanostim Leadless Pacemaker (LP), model number S1DLCP. The Nanostim LP device has not been manufactured or implanted since November 02, 2016. However, the Nanostim LP (model S1DLCP) is currently implanted in patients and in the event these devices need to be retrieved, the Aveir Retrieval Catheter can be used.

The Aveir Retrieval Catheter is intended to be used to retrieve an LP and to be manipulated by a single operator that allows the operator to perform these actions:

- Advance the Retrieval Catheter from an access site in the groin (utilizing minimally invasive techniques) through the femoral vein into the heart.
- Steer and position the snare towards the docking button of the LP.
- Snare the docking button of the LP.
- Dock the Retrieval Catheter to the LP.
- Rotate the LP to unscrew the LP helix from the endocardium.
- Protect the LP helix and electrode during retrieval.
- Extract the LP through the access site in the groin.

Apart from the docking mechanism, the Retrieval Catheter and its control system (handle) have the same operating principle as a conventional steerable catheter and control system, while the snare mechanism and dimensions are similar to commercially available snares systems. The Retrieval Catheter is intended to be used with the compatible Aveir Introducer.

The Retrieval Catheter effective length is 105 cm (41.3 in) and the snare loop inner diameter is 16.5mm (0.65 in). The technical details and materials used in this product can be found in the Instructions for Use.

VI. INDICATIONS FOR USE / INTENDED USE

The Aveir™ Retrieval Catheter is intended to be used in the peripheral vasculature and the cardiovascular system to retrieve and manipulate an Abbott Medical leadless pacemaker (LP). Retrieval and manipulation includes removing the LP from the heart or peripheral vasculature.

The proposed indications for the Aveir Retrieval Catheter are not identical to the predicate devices; however, the differences do not alter the intended therapeutic use of the device relative to the predicates. Both the subject and the predicate devices share the same intended purpose of retrieving and manipulating foreign objects from the cardiovascular system (Primary Predicate Device EN Snare® Endovascular Snare System (K092343)), including the peripheral vascular (ONE Snare™ (K122088)) and femoral vein (Crux Snare Filter Retrieval Set (K133681)).

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Retrieving and manipulating foreign objects from the cardiovascular system is the technological principle for both the subject and predicate devices. It is based on manipulation of a snare (opening, closing, rotating) from within an outer catheter. The snare can be positioned near the object and closed to manipulate or retrieve the object.

The subject and predicate devices are based on the following technological elements that are the same:

- Single-use devices
- Snare introduced via conventional venous access through Pebax catheters
- Snare comprised of Nitinol cable loop(s) secured to a shaft
- Radiopaque features on snare and catheter provide physician with visibility during fluoroscopy
- The snare is controllable by advancing and retracting, or rotating, the snare or catheter to a position close to the object to be retrieved
- When the snare is appropriately positioned, the snare can be closed onto object by advancing a sheath, catheter or tube over the snare
- Ability to torque snare
- Ability to manipulate a foreign body
- Ability to retrieve snared foreign body into a guide catheter or sheath for removal through the vasculature
- Catheter length of subject device within range established by the predicates
- Pre-formed snare loop size of subject device within range established by the predicates

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

- The predicate devices are comprised of individual components (snare, catheter/sheath, snare introducer, torque device) that are assembled into a system by the user at time of use, while the Aveir Retrieval Catheter subject device is comprised of similar components (snare, steerable/deflectable catheter, valve bypass tool (snare introducer), integrated guide catheter) pre-assembled into a single catheter.
- The catheter of the Primary Predicate device (EnSnare) is pre-shaped with an angled tip, while the Aveir Retrieval Catheter can be deflected during use per the user's needs.

VIII. PERFORMANCE DATA

The Aveir™ Retrieval Catheter 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 as safe and effective for its intended use.

Biocompatibility Testing

The biocompatibility evaluation for the Aveir™ Retrieval Catheter was conducted in accordance with ISO10993-1 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™ Retrieval Catheter is considered an external medical device in contact with circulating blood for less than 24 hours per ISO 10993-1 guidelines.

The testing included the following:

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

Non-Clinical Testing

Design Verification and validation testing was performed to ensure that the Aveir Retrieval Catheter met the design specifications and user needs. The testing included:

- Physical and Dimensional Characteristics
- Tensile Strength
- Torsional Strength
- Deflection
- Simulated Use
- Liquid Leak
- Corrosion Resistance
- Packaging (ASTM D4332-16) and Shelf Life Testing

- Nominal T=0
- Accelerated Aging

Animal Testing and Human Factors

Usability validation testing including the Aveir Retrieval Catheter was conducted. The usability acute study was conducted for the intended use workflows where the Aveir Retrieval catheter is utilized along with an Introducer to retrieve an LP via femoral vein. Based on the results of usability validation testing, the Aveir Retrieval Catheter 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.

In addition, a 182-day Chronic GLP Retrieval Study was performed to demonstrate the safety of retrievability of Aveir Leadless Pacemaker devices at least 182 days post-implant. 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 ovine subjects were implanted with Aveir Leadless Pacemakers. The subjects had their Aveir Leadless Pacemaker devices successfully retrieved (100% retrieval success rate) using the Aveir Retrieval Catheter by physician operators. All physicians evaluated the safety and performance of the Aveir Retrieval Catheter rated it as good and acceptable or very good and acceptable. Per the board-certified veterinary study pathologist, the gross changes seen at the implant sites in chronically-implanted animal after Leadless Pacemaker retrieval were consistent with atraumatic removal by unscrewing of the device in a counterclockwise manner from the implant site in all animals. All implant sites remained intact following retrieval with an absence of significant trauma and injury to the IVC, right heart, and tricuspid valve apparatus. No retrieval procedure-related or device-related gross changes were seen in draining lymph nodes (pericardial, subaortic, mediastinal, and tracheobronchial).

In summary, these studies demonstrated that the Aveir Retrieval Catheter can safely manipulate and retrieve a foreign object (Aveir LP) from the cardiovascular system.

Clinical Testing

Clinical evaluation is not required for the Aveir Retrieval Catheter.

IX. CONCLUSIONS

The resulting evidence obtained from the non-clinical data support the safety of the device and that the Aveir Retrieval Catheter should perform as intended in the specified conditions. The design verification and validation testing demonstrated that the Aveir Retrieval Catheter device performs comparably to the primary predicate device that is currently marketed with the same design features.

Based on the indications for use, technical characteristics, safety, and performance testing, the Aveir Retrieval Catheter is substantially equivalent to the primary predicate EN Snare Endovascular Snare System (K092343), and reference devices Merit ONE Snare System (K122088) and Crux Snare Filter Retrieval Set (K133681). Any differences in the technological characteristics between the devices do not raise any new issues of safety or effectiveness as compared to the predicate device.