June 30, 2022

Abbott Medical
Indira Verdekel
Regulatory Affairs Project Manager
15900 Valley View Court
Sylmar, California 91342

Re: K221750
Trade/Device Name: CPS AIM Universal II Slittable Inner Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 15, 2022
Received: June 16, 2022

Dear Ms. Verdekel:

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)*
K221750

Device Name
CPS AIM™ Universal II Slittable Inner Catheter

Indications for Use *(Describe)*
The CPS Aim™ Universal II slittable inner catheter (subselector/cannulator) is designed for intracardiac access of the coronary sinus and subselection of the venous system of the heart, and to serve as a conduit during implantation for delivery of contrast medium and Abbott Medical devices (such as guidewires and implantable left heart leads). In addition, the CPS Aim™ Universal II slittable inner catheter (subselector/cannulator) can work with outer guide catheters as a 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.

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510(k) Summary

Date Prepared

June 15, 2022

Submitter

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Device

Name of Device:	CPS Aim™ Universal II Slittable Inner Catheter
Model Numbers:	DS2N100-59, DS2N100-65, DS2N101-59, DS2N101-65, DS2N102-59, DS2N102-65, DS2N103-65, DS2N104-65
Common or Usual Name:	Percutaneous catheter
Classification Name:	Catheter Introducer (21 CFR 870.1250)
Regulatory Class:	Class II
Code:	DQY

Predicate Device

The line extension, CPS Aim™ Universal II Slittable Inner Catheter, is substantially equivalent in intended use and method of operation to the following predicate manufactured by Abbott Medical.

- CPS Aim™ Universal Slittable Inner Catheter (K130252, cleared on March 20, 2013)

Device Description

The CPS Aim™ Universal II Slittable Inner Catheter (subselector/cannulator) is used to facilitate left heart lead delivery procedures. It is an introducer that is used to cannulate the coronary venous system and act as a conduit for contrast medium, implantable coronary leads, or other devices.

The CPS Aim™ Universal II Slittable Inner Catheter design is based on the currently marketed CPS Aim™ Universal Slittable Inner Catheter design and components. Three modifications were made:

1. Modified hydrophilic coating: the subject device uses a different hydrophilic coating material as compared to the currently marketed CPS Aim Universal catheters.
2. Use of a modified braid design pattern to provide improved kink resistance: the predicate device braid is a single braided wire, and the subject braid contains paired braided wires.
3. Reduction in shelf-life from three (3) years to two (2) years.

The CPS Aim™ Universal II Slittable Inner Catheter will be added as a line extension to the currently marketed family of CPS catheters. New, unique model numbers will distinguish the CPS Aim™ Universal II inner catheter models from existing CPS catheter models.

The CPS Aim™ Universal II Slittable Inner Catheters will be available in the same working lengths, 59 cm and 65 cm, as the predicate device, and will be available with the same shape of curves as the predicate device. The key design features of the CPS Aim™ Universal II Slittable Inner Catheters have only undergone a minimal change to support the coating and braid change. There is no change to the accessories, including the slitter and valve bypass tool (VBT).

The key design features CPS Aim Universal and CPS Aim Universal II Slittable Inner Catheters and their accessory, the CPS Valve Bypass Tools include:

- Braid reinforced, varying durometer PEBAX catheter shaft with molded proximal hub.
- Inner diameter of the catheter is PTFE lined.
- Atraumatic distal soft tip.
- Embedded marker band on soft tip for fluoroscopic visibility.
- Outside surface of the catheter shaft is coated with a hydrophilic coating to provide lubricity during use.
- Hub of the catheter is fitted with a retention cap and an integrated valve that provides hemostasis and facilitates contrast injection. The hub also includes a sideport assembly with 3-way stopcock.
- The catheters are available in cannulator and sub-selector models.
- Accessories such as valve bypass tool (VBT) used to assist the insertion of Abbott Medical devices (leads, guidewires, inner catheters, etc.).

Similar to the existing CPS catheters, the CPS Aim™ Universal II Slittable Inner Catheters are supplied sterile (via ethylene oxide) in one package and are intended for single procedure.

There is no change in accessory product or process for the different models as a result of this line extension. The proposed indications for use is consistent with the cleared indications.

Pediatric Use

The CPS Aim™ Universal II Slittable Inner Catheter products have not been studied in pediatric patients.

Indications for Use

The are no changes to the Indications for Use as a result of this submission. The Indications for Use for the CPS Aim™ Universal II Slittable Inner Catheter is as follows:

> The CPS Aim™ Universal II Slittable Inner Catheter (subselector/cannulator) is designed for intracardiac access of the coronary sinus and subselection of the venous system of the heart, and to serve as a conduit during implantation for delivery of contrast medium and Abbott Medical devices (such as guidewires and implantable left heart leads). In addition, the CPS Aim™ Universal II Slittable Inner Catheter (subselector/cannulator) can work with outer guide catheters as a system.

Comparison of Technological Characteristics with Predicate Device

The CPS Aim™ Universal II Slittable Inner Catheter has the same technological characteristics as the currently marketed CPS Aim™ Universal Slittable Inner Catheter with minor changes to the hydrophilic coating and braid. Where differences exist between the subject device and the predicate device, performance testing demonstrated that the CPS Aim™ Universal II Slittable Inner Catheter performs in a substantially equivalent manner to the currently marketed predicate device.

Performance Data

The CPS Aim™ Universal II Slittable Inner 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 as the predicate devices:

Biocompatibility Testing

The biocompatibility evaluation for the CPS Aim™ Universal II Slittable Inner Catheter 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. Based on the ISO and FDA guidelines, the nature of patient contact for the CPS Aim™ Universal II Inner Catheter are externally communicating device with limited (≤24 hours) circulating blood contact. The Valve Bypass Tools are externally communicating, devices with limited (≤24 hour) indirect blood contact.

The testing included the following:

- Cytotoxicity
- Sensitization, Irritation
- Materials-Mediated Pyrogenicity
- Acute Systemic Toxicity
- Hemocompatibility (Direct Contact and Extract)
- Complement Activation Assay – SC5b-9
- Partial Thromboplastin Time
- Platelet & Leukocyte Counts
- Particulate Matter per USP <788>
- Surface Characterization

Bench Testing

- Design Verification
    - Physical and Dimensional Characteristics
    - Functional Characteristics
    - Particulate Testing
    - Hydrophilic Coating Lubricity and Durability
- Shelf-Life Testing
    - Accelerated Aging 24-month (device)

Conclusions

The resulting evidence obtained from the design verification testing and the risk analysis demonstrated that the subject device is as safe and effective as the predicate device, the CPS Aim™ Universal Slittable Inner Catheter (K130252).