June 2nd, 2023

Abbott Medical
Mary Adams
Regulatory Affairs Consultant
15900 Valley View Court
Sylmar, California 91342

Re: K231311
Trade/Device Name: CPS Direct™ Universal slittable outer guide catheter (DS2C029)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 5, 2023
Received: May 5, 2023

Dear Mary Adams:

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,

Lydia S. Glaw -S

Digitally signed by Lydia S. Glaw -S
Date: 2023.06.02 12:11:54 -04'00'

Lydia Glaw
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

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)*

K231311

Device Name

CPS Direct™ Universal slittable outer guide catheter (DS2C029)

Indications for Use *(Describe)*

The CPS Direct™ Universal slittable outer guide catheter is designed for intracardiac access of the venous system of the heart and to serve as a conduit during implantation for the delivery of contrast medium and other devices (including implantable left heart leads and delivery tools), and support of fluids where minimizing blood loss is essential. In addition, the CPS Direct Universal slittable outer guide catheters can work with inner 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

Prepared on: 2023-05-05

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	(909) 991-5235
Applicant Contact	Ms. Mary Adams
Applicant Contact Email	mary.adams2@abbott.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	CPS Direct™ Universal slittable outer guide catheter (DS2C029)
Common Name	Percutaneous catheter
Classification Name	Catheter, Percutaneous
Regulation Number	870.1250
Product Code	DQY

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K130257	CPS Direct™ Universal Slittable Outer Catheter	DQY

Device Description Summary

21 CFR 807.92(a)(4)

The device description of the CPS Direct™ Universal slittable outer guide catheter, 3D, is as follows.
• The CPS Direct™ Universal slittable outer guide catheter facilitates left heart lead delivery during cardiac resynchronization therapy (CRT) procedures. The CPS Direct Universal provides access to the coronary venous system and acts as a conduit for contrast medium. The key design features of the CPS Direct™ Universal slittable outer guide catheter, 3D, has only undergone minimal changes to the shaft length, the curve design, and the package tray configuration. The dilator packaged with the catheter has undergone a change in shaft length to accommodate the shaft length of the 3D catheter. The accessories listed in the device instructions for use have not changed. The key design features of the catheter are listed below:
• Braid reinforced, varying durometer PEBAX shaft with molded proximal hub.
• Atraumatic distal soft tip.
• The outside surface and inside surfaces of the catheter shaft are coated with Siloxane to provide lubricity during use.
• The distal end of the shaft has gold marker bands and tungsten stripes for fluoroscopic visibility.
• Hub contains a sideport with extension tubing for contrast delivery, aspiration, or saline flush using a 3-way stopcock.
• Accessories such as VBT used to assist the insertion of Abbott Devices (leads, guidewires, inner catheters, etc)

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The CPS Direct™ Universal slittable outer guide catheter is designed for intracardiac access of the venous system of the heart and to serve as a conduit during implantation for the delivery of contrast medium and other devices (including implantable left heart leads and delivery tools), and support of fluids where minimizing blood loss is essential. In addition, the CPS Direct Universal slittable outer guide catheters can work with inner catheters as a system.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device CPS Direct™ Universal slittable outer guide catheter model DS2C029 (3D curve) has the following similarities to the predicate device model (DS2C029 extra wide curve) which previously received 510(k) concurrence (K130257):
• Has the same indicated use,
• Has the same fundamental scientific technology,
• Incorporates the same basic catheter design,
• Incorporates the same catheter construction,
• Incorporates the same device and packaging materials, including sterile barrier,
• Is sterilized using the same processes (EtO with SAL of at least 10^-6 per ISO 11135-1).

In summary, the CPS Direct Universal slittable outer guide catheter model DS2C029 (3D curve) described in this submission is substantially equivalent to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

The subject CPS Direct™ Universal slittable outer guide catheter model DS2C029 (3D curve) has the same technological characteristics as the currently marketed CPS Direct™ Universal slittable outer guide catheter model DS2C029 (X-Wide curve), with only minimal changes to the catheter, dilator and packaging design, and meets current regulatory requirements and standards.

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

The modifications to the CPS Direct™ Universal 3D slittable outer guide catheter and packaging, i.e., catheter length, dilator length, catheter curve shape, and packaging tray, necessitated limited functional and packaging design verification (DV) testing, compatibility testing, and a sterilization adoption assessment study. Completion of all verification and validation activities demonstrated that the modified catheter with associated components meets its predetermined design and performance specifications, and that the subject CPS Direct™ Universal slittable outer guide catheter model DS2C029 (3D curve) is substantially equivalent to the predicate device.