November 24, 2021

Marybeth Gamber
VP, Regulatory/Quality
CenterPoint Systems LLC
3338 Parkway Blvd
West Valley City, Utah 84119

Re: K210009
Trade/Device Name: Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 22, 2021
Received: October 25, 2021

Dear Marybeth Gamber:

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 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.

510(k) Number *(if known)*
K210009

Device Name
Guiding Catheter

Indications for Use *(Describe)*
The Guiding Catheter is indicated to provide a pathway through which therapeutic devices are introduced. The catheter is intended to be used in the peripheral 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.

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."

Traditional 510(k) Premarket Notification Submission: Guiding Catheter (K210009)

1 510(K) SUMMARY

1.1 Submitter

Name	CenterPoint Systems LLC
Address	3338 Parkway Blvd West Valley City UT 84119
Phone	877-848-0828
Contact Person:	Marybeth Gamber, Vice President Regulatory Affairs & Quality Assurance
Date Prepared:	November 23, 2021

1.2 Device

Name of Device:	Guiding Catheter
Common or Usual Name	Guide Catheter
Classification Name:	Catheter, Percutaneous
Regulatory Class:	Class II per 21 CFR 870.1250
Product Code:	DQY

1.3 Predicate Device

Predicate Name and 510(k) Number: Medtronic Launcher Guide Catheter, K022764

This predicate has not been subject to a design-related recall.

No reference predicates were used in this submission.

1.4 Device Description

The Guiding Catheter is a single-use percutaneous catheter intended to be used in the peripheral vascular system to provide a pathway through which therapeutic devices are introduced.

The Guiding Catheter is available in a variety of curves to accommodate various anatomies. The Guiding Catheter is comprised of a braid-reinforced catheter shaft terminating in an atraumatic, radiopaque tip. The device includes a proximal hub with luer fitting for fluid infusion and/or aspiration as well as strain relief. The catheter is a single use disposable device. The Guiding Catheter has an inner diameter of 6F, an outer diameter of 7F, and is compatible with an 0.035" guidewire.

1.5 Indications for Use

The Guiding Catheter is indicated to provide a pathway through which therapeutic devices are introduced. The catheter is intended to be used in the peripheral vascular system.

1.6 Comparison of Technological Characteristics with the Predicate Device

The Proposed Device and Predicate Device are similar in indications for use, intended use, technological characteristics, and principles of operation.

The differences between the Proposed Device and the Predicate Device are minor and raise no different questions of safety and effectiveness, thus it was concluded that the Proposed Device is substantially equivalent to the Predicate Device. In accordance with 21CFR807.92(a)(6) a summary of how the technological characteristics of the Proposed Device compares to the Predicate Device is provided below.

Feature	**Guiding Catheter (proposed device)**	**Medtronic Launcher Guide Catheter (K022764)**
Intended Use	Percutaneous catheter for the delivery of therapeutic devices	Same
Indications for Use	The Guiding Catheter is indicated to provide a pathway through which therapeutic devices are introduced. The catheter is intended to be used in the peripheral vascular system.	The Medtronic Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The Launcher catheter is intended to be used in the coronary or peripheral vascular system. Substantially Equivalent: The proposed device does not include the coronary indication. Otherwise the indications for use are identical.
Device Class	Class II	Same
Product Code	DQY, 21 CFR 870.1250	Same
Prescription device	Yes	Same
Catheter Type	Percutaneous Catheter	Same
Guidewire compatibility	0.035”	Same
Catheter Outer Diameter	7.0F	Same
Catheter Inner Diameter	6.0F	Same
Catheter Length	55cm	Same
Low Friction Liner	Yes	Same
Radiopaque Catheter Distal Tip	Yes	Same
Braided Shaft Encapsulated in polymer	Yes	Same
Female luer hub with Strain Relieve	Yes	Same
Multiple Distal End Shapes Available	Yes	Same
Sterility	Provided Sterile	Same
Number of uses	Single patient use	Same

Feature	Guiding Catheter (proposed device)	Medtronic Launcher Guide Catheter (K022764)
Principles of Operation	After percutaneous access is gained, the catheter is advanced over a guidewire to the desired location. A therapeutic is placed through the Guiding Catheter. The Guiding Catheter is removed using standard technique.	Same

The Guiding Catheter is used for the same intended use in the same anatomical location using the same principles of operation as the predicate device. Both the Guiding Catheter and the predicate use the same types of medical grade materials in the construction of the devices. This includes an inner liner, stainless steel braid, outer shaft jacket, a soft distal tip, and a female luer hub with strain relief. The substantial equivalence decision was also established based on the technical evaluation of attributes of the proposed and predicate devices. Therefore, the Guiding Catheter can be considered substantially equivalent to the predicate device.

1.7 Performance Data

All necessary performance testing has been conducted on the Guiding Catheter to assure substantial equivalence to the predicate devices and to demonstrate the device performs as intended. All testing was performed on test units representative of finished devices.

The device passed the following tests, which were conducted in accordance with noted standards:

Test	Consensus Standard/FDA Guidance/Description
Biocompatibility	FDA Final Guidance Document, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" (June 2016)
Bench testing, including dimensional evaluation, tensile testing, torque testing, kink resistance testing, packaging testing, tip joint fatigue testing, burst proof testing, high pressure dynamic testing, particulate testing.	Confirm that the device meets intended product specifications
Simulated Use testing	Confirm that the device will perform as intended in a simulated environment
In Vivo Testing	Confirm the device will perform as intended in an *in vivo* model.

1.8 Conclusions

Upon reviewing the information provided in this submission and comparing the intended use, principle of operation and overall technological characteristics, the Guiding Catheter is substantially equivalent to existing legally marketed devices.