June 28, 2019
CenterPoint Systems
Marybeth Gamber
Vice President, Regulatory & Quality
3338 Parkway Blvd
West Valley City, Utah 84119

Re: K190475
Trade/Device Name: Delivery Catheter SSPC1, Delivery Catheter SSPC2, Delivery Catheter SSPC3, Delivery Catheter SSPC4
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 4, 2019
Received: June 5, 2019

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,

for

Jessica Paulsen
Implantable Electrophysiology Devices Team
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190475

Device Name
Delivery Catheter

Indications for Use *(Describe)*
The Delivery Catheter is indicated for the introduction of various types of catheters and pacing or defibrillator leads.

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.

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"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."

5 510(K) SUMMARY

5.1 Submitter

Name	CenterPoint Systems
Address	3338 Parkway Blvd West Valley City UT
Phone	877-848-0828
Contact Person:	Marybeth Gamber, Vice President Regulatory Affairs & Quality Assurance
Date Prepared:	February 26, 2019

5.2 Device

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

5.3 Predicate Device

Predicate Name and 510(k) Number: Medtronic C315 Delivery Catheter, K101885

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

No reference predicates were used in this submission.

5.4 Device Description

The Delivery Catheter is a single-use percutaneous catheter intended to introduce various types of catheters and pacing or defibrillator leads.

The Delivery Catheter is packaged with a dilator for introduction into the vasculature. Proximally, the Delivery Catheter is equipped with a hemostatic valve, and the distal soft, rounded, radiopaque tip facilitates imaging under fluoroscopy. The Delivery Catheter is designed to be slittable, thereby allowing its removal after device placement. A variety of curves and lengths are available to accommodate various anatomies and different lead locations. The Delivery Catheter has an inner diameter of 6.5F, an outer diameter of 8F, and the dilator is compatible with a 0.035” guidewire

5.5 Indications for Use

The Delivery Catheter is indicated for the introduction of various types of catheters and pacing or defibrillator leads.

5.6 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, 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	**Delivery Catheter (proposed device)**	**Medtronic C315 Delivery Catheter (K101885)**
Intended Use	Percutaneous catheter for the delivery of catheters and leads	Same
Indications for Use	The Delivery Catheter is indicated for the introduction of various types of catheters and pacing or defibrillator leads.	Same
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	8.0F	7.0F Substantially equivalent
Catheter Inner Diameter	6.5F	5.4F Substantially equivalent
Catheter Length	30 - 40cm	20 – 43cm Substantially equivalent
Hydrophilic Liner	Yes	Same
Radiopaque Catheter Distal Tip	Yes	Same
Hemostasis valve	Yes	Same
Components Provided	Catheter, Dilator	Same
Multiple Distal End Shapes Available	Yes	Same
Sterility	Provided Sterile	Same
Number of uses	Single patient use	Same

Feature	Delivery Catheter (proposed device)	Medtronic C315 Delivery Catheter (K101885)
Principals of Operation	After venous access is gained, the catheter and dilator are advanced over a guidewire to the desired location. The dilator is removed and a catheter or lead is placed through the Delivery Catheter. The Delivery Catheter may be removed by slitting.	Same

The Delivery Catheter is used for the same intended use in the same anatomical location using the same principles of operation as the predicate device. Therefore, the Delivery Catheter can be considered substantially equivalent to the predicate device.

5.7 Performance Data

All necessary performance testing has been conducted on the Delivery 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, etc	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.

5.8 Conclusions

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