June 18, 2025

CenterPoint Systems LLC
Conner Johnson
Senior Regulatory Specialist
3338 Parkway Blvd
West Valley City, Utah 84119

Re: K250492
Trade/Device Name: FlexiGo 3D Delivery Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 20, 2025
Received: May 20, 2025

Dear Conner Johnson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

ALEXANDRA K. MANARAS -S

For Sara Royce
Assistant Director
DHT2A: Division of Cardiac Electrophysiology, Diagnostics, and Monitoring 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250492

Device Name

FlexiGo 3D Delivery Catheter

Indications for Use *(Describe)*

The Delivery Catheter is intended for the venous introduction of pacing or defibrillation 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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."

510(k) Summary

1.1 Submitter

Name	CenterPoint Systems LLC
Address	3338 Parkway Blvd West Valley City UT
Phone	801-602-1923
Contact Person:	Conner Johnson, Senior Regulatory Specialist
Date Prepared:	10 February 2025

1.2 Device

Name of Device:	FlexiGo 3D Delivery Catheter
Classification Name:	Percutaneous Catheter
Regulatory Class:	Class II per 21 CFR 870.1250
Product Code:	DQY

1.3 Predicate Device

Predicate Name and 510(k) Number: SSPC Delivery Catheter, K190475

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

1.4 Device Description

The modified Delivery Catheter (FlexiGo 3D Delivery Catheter) is a single-use percutaneous catheter intended for venous introduction of pacing or defibrillation leads.

The modified Delivery Catheter is packaged with a dilator and two (2) trans vavular introducers for introduction into the vasculature. Proximally, the modified Delivery Catheter is equipped with a hemostatic valve, and the distal soft, rounded, radiopaque tip facilitates imaging under fluoroscopy. The modified 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 locations.

1.5 Indications for Use

The Delivery Catheter is intended for the venous introduction of pacing or defibrillation leads.

1.6 Comparison of Technological Characteristics with the Predicate Devices

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. 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	**FlexiGo 3D Delivery Catheter (subject device)**	**Primary Predicate: SSPC Delivery Catheter (K190475)**	**Same / Different between Proposed & Predicates**
Intended Use	**Percutaneous catheter for the delivery of leads**	**Percutaneous catheter for the delivery of** catheters and **leads**	Substantially equivalent
Indications for Use	**The Delivery Catheter is intended for the** venous **introduction of pacing or defibrillation leads**	**The Delivery Catheter is intended for the introduction of** various types of catheters and **pacing or defibrillator leads.**	Substantially equivalent
Product Code	DQY	DQY	Same
Regulation number	21 CFR 870.1250	21 CFR 870.1250	Same
Prescription Device	Yes	Yes	Same
Catheter Type	Percutaneous Catheter	Percutaneous Catheter	Same
Guidewire Compatibility	0.035”	0.035”	Same
Outer Diameter	8.0F, 9.5F	8.0F	Substantially Equivalent
Inner Diameter	5.9F, 7.4F	6.5F	Substantially Equivalent
Working Length	40cm, 41cm, 45cm	40cm	Substantially Equivalent
Components Provided	Catheter, Dilator, Luer cap, TVIs	Catheter, Dilator, Luer cap	Substantially Equivalent
Hydrophilic Liner	Yes	Yes	Same
Valve	Yes	Yes	Same
Shaft Materials	PEBAX with Barium Sulfate and colorants	PEBAX with Barium Sulfate and colorants	Same
Braid Reinforcement	Yes	Yes	Same

Feature	FlexiGo 3D Delivery Catheter (subject device)	Primary Predicate: SSPC Delivery Catheter (K190475)	Same / Different between Proposed & Predicates
Dilator	Yes	Yes	Same
Multiple Distal End Shapes Available	Yes	Yes	Same
Sterility	E-Beam Sterilization, SAL 10^{-6}	E-Beam Sterilization, SAL 10^{-6}	Same
Number of Uses	Single patient use	Single patient use	Same
Principles 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 lead is placed through the Delivery Catheter. The Delivery Catheter may be removed by slitting.	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 modified Delivery Catheter is used for the same intended use in the same anatomical location using the same principles of operation as the predicate device.

1.7 Performance Data

All necessary performance testing has been conducted on the SSPC NXT 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:

- Biocompatibility testing per 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" (2023)
- Sterilization validation per ISO 11137
- Packaging validation per ANSI/AAMI/ISO 11607-1
- Visual Inspection
- Simulated use testing, including use/compatibility with ancillary devices
- Valve liquid leak test
- Tensile tests
- Sheath and Dilator Dimensional verification, including OD/ID, working length
- Flush test

1.8 Conclusions

Based on the similarity of the subject and predicate devices in terms of the intended use, principle of operation and overall technological characteristics, and the results of the testing summariezed in section 1.7, the FlexiGo 3D Delivery Catheter is substantially equivalent to the predicate device (K190475).