April 7, 2026

CenterPoint Systems
Conner Johnson
Director of Regulatory
3338 Pkwy. Blvd.
West Valley City, UT 84119

Re: K260942
Trade/Device Name: AuST Steerable Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: March 16, 2026
Received: March 20, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MISTI L. MALONE -S

Misti Malone, PhD
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K260942

Device Name
AuST Steerable Sheath

Indications for Use *(Describe)*
The AuST Steerable Sheath is intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal and other peripheral placements. Do not use this device for neural placements.

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.

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, Director of Regulatory
Date Prepared:	20 March 2026

1.2 Device

Name of Device:	AuST Steerable Sheath
Classification Name:	Catheter Introducer
Regulatory Class:	Class II per 21 CFR 870.1340
Product Code:	DYB

1.3 Predicate Device

Predicate Name and 510(k) Number: AuST Steerable Sheath, K251051

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

1.4 Device Description

The AuST Steerable Sheath is a single-use percutaneous catheter intended to provide a pathway through which diagnostic and therapeutic devices are introduced in the human vasculature. The catheter is not intended for neural placements.

The AuST Steerable Sheath product family consists of a variety of configurations to accommodate different anatomies and/or devices being introduced into the human vasculature. Each of the sheaths in the product family is comprised of a braid-reinforced catheter shaft, deflectable segment, radiopaque distal tip, a handle with a 3-way stopcock for flushing and aspiration, and a hemostasis valve to prevent air and fluid leakage.

1.5 Indications for Use

The AuST Steerable Sheath is intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal and other peripheral placements. Do not use this device for neural placements.

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 involve the addition of some model configurations, including an external silicone lubricant, modified valve and handle designs. 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	**Modified AuST Steerable Sheath (proposed device)**	**Primary Predicate: AuST Steerable Sheath (K251051)**	**Same / Different between Proposed & Predicates**
Intended Use/Indications for Use	The modified AuST Steerable Sheath is **intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal and other peripheral placements. Do not use this device for neural placements.**	The currently cleared AuST Steerable Sheath (K251051) is **intended for the introduction of diagnostic and therapeutic devices into the human vasculature, including but not limited to intracardiac, renal and other peripheral placements. Do not use this device for neural placements.**	Same
Device Class	II	II	Same
Product Code	DYB	DYB	Same
Regulation number	21 CFR 870.1340	21 CFR 870.1340	Same
Duration of use	Single-use, Transient	Single-use, Transient	Same
Sterilization	Ethylene Oxide	Ethylene Oxide	Same
Prescription Device	Yes	Yes	Same
Inner Diameter / Outer Diameter	4 available: 8.5F (OD: 13F), 10F (OD: 14.9F), 12F (OD: 16.3F), 13.2F (OD: 17.4F)	4 available: 8.5F (OD: 13F), 10F (OD: 14.9F), 12F (OD: 16.3F), 13.2F (OD: 17.4F)	Same
Active Length (Sheath)	44cm, 65cm, 74cm and 84cm	44cm, 65cm, 74cm and 84cm	Same
Deflection (Degree)	Yes (180 degrees, bi-driectional)	Yes (180 degrees, bi-driectional)	Same

Feature	Modified AuST Steerable Sheath (proposed device)	Primary Predicate: AuST Steerable Sheath (K251051)	Same / Different between Proposed & Predicates
Guidewire Compatibility	Max outside diameter 0.89mm (0.035”)	Max outside diameter 0.89mm (0.035”)	Same
Tip with Radiopaque Materials	Yes	Yes	Same
Materials/ Biocompatibility	Standard medical device materials, including PEBAX, PTFE, Stainless Steel, Vestamid Standard medical device materials. The biocompatibility tests demonstrate that there are no adverse biocompatibility risks associated with use of this material. All test results met the requirements of ISO 10993-1.	Standard medical device materials, including PEBAX, PTFE, Stainless Steel, Vestamid Standard medical device materials. The biocompatibility tests demonstrate that there are no adverse biocompatibility risks associated with use of this material. All test results met the requirements of ISO 10993-1.	Same
Coatings / Lubricants	External: Some models have silicone oil lubricant on the distal outer diameter of the sheath and dilator Internal: The inner diameter of the sheath is lined with a hydrophilic coated liner or a low friction uncoated liner.	External: None Internal: The inner diameter of the sheath is lined with a hydrophilic coated liner or a low friction uncoated liner.	Substantially Equivalent
Handle Design	Additional handle design with modified color and ergonomic shape	One handle design	Substantially Equivalent

Feature	Modified AuST Steerable Sheath (proposed device)	Primary Predicate: AuST Steerable Sheath (K251051)	Same / Different between Proposed & Predicates
Valve Design	Models will have one of three valve designs: (2) two-part valves and (1) three-part valve. The three-part and a two-part valve are bonded prior to being secured in the hub. The other two-part valve is not bonded prior to being secured in the hub.	Models will have one of two valve designs, both of which are two-part valves. One of the two-part valves is bonded prior to being secured in the hub. The other two-part valve is not bonded prior to being secured in the hub.	Substantially equivalent.
Features	Bi-directional Deflectable Sheath, Soft Atraumatic Tip with ventilation holes, Handle with Deflection Control, Hemostasis Valve, Side Port (Irrigation/Aspiration), Dilator	Bi-directional Deflectable Sheath, Soft Atraumatic Tip with ventilation holes, Handle with Deflection Control, Hemostasis Valve, Side Port (Irrigation/Aspiration), Dilator	Same

The AuST Steerable Sheath 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 AuST Steerable Sheath to assure substantial equivalence to the predicate device 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:

- Simulated use testing, including:
    - Device preparation
    - Dilator shoulder extension
    - Guidewire passage
    - Deflection with dilator
    - Valve liquid leak test
    - Flush Test
    - Navigation and access for ancillary devices
- Tensile tests
- Torque test
- Dilator tip cycling
- Particulate evaluation
- Biocompatibilty testing in accordance to ISO 10993

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, the modified AuST Steerable Sheath is substantially equivalent to the predicate device.