August 31, 2021

Talon Surgical
Jay Muse
President and CEO
6030 West Harold Gatty Drive
Salt Lake City, Utah 84116

Re: K210185
Trade/Device Name: CardioCurve™ Steerable Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB

Dear Jay Muse:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 23, 2021. Specifically, FDA is updating this SE Letter to include your 510(k) Summary as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Aneesh Deoras, OHT2: Office of Cardiovascular Devices, at 240-402-4363 or aneesh.deoras@gmail.com.

Sincerely,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director (Acting)
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

July 23, 2021

Talon Surgical
Jay Muse
President and CEO
6030 West Harold Gatty Drive
Salt Lake City, Utah 84116

Re: K210185
Trade/Device Name: CardioCurve™ Steerable Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: June 17, 2021
Received: June 21, 2021

Dear Jay Muse:

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,

Aneesh S. Deoras -S

Aneesh Deoras
Assistant Director (Acting)
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210185

Device Name
CardioCurve™ Steerable Sheath

Indications for Use *(Describe)*
The Talon Surgical CardioCurve™ Steerable Sheath is indicated when introducing various cardiovascular devices to the epicardial or endocardial surfaces of the heart, including the left side of the heart through the interatrial septum.

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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6030 West Harold Gatty Drive, Salt Lake City, UT 84116
Ph: 801-210-2886

510(K) SUMMARY

K210185

Submitter:

Talon Surgical
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6030 West Harold Gatty Drive
Salt Lake City, UT 84116
Telephone: 801-210-2886
Email: jay.muse@talonsurgical.com

Primary Contact:

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6030 West Harold Gatty Drive
Salt Lake City, UT 84116
Telephone: 801-210-2886
Email: jay.muse@talonsurgical.com

DATE PREPARED:

January 19, 2021

NAME OF MEDICAL DEVICE:

Proprietary Name:	CardioCurve™ Steerable Sheath
Common/Usual Name:	Catheter Introducer
Classification Name:	Introducer, Catheter
510(k) Number:	K210185

DEVICE CLASSIFICATION:

Classification Panel:	Cardiovascular
Regulatory Class:	II
Product Code:	DYB
Regulation Number:	21 CFR 870.1340

PREDICATE DEVICES:

Proprietary Name:	Agilis NxT Steerable Introducer
Common/Usual Name:	Catheter Introducer
Classification Name:	Introducer, Catheter
510K Number:	K110450

REFERENCE DEVICES:

Proprietary Name:	Agilis PF Introducer System and accessories
Common/Usual Name:	Catheter Introducer
Classification Name:	Introducer, Catheter
510K Number:	K111943

Proprietary Name:	Agilis NxT Steerable Introducer
Common/Usual Name:	Catheter Introducer
Classification Name:	Introducer, Catheter
510K Number:	K081645

DEVICE DESCRIPTION:

The Talon Surgical CardioCurve Steerable Sheath is a 8.5F sterile, single-use, catheter introducer used for the introduction, withdrawal, and exchange of guidewires and catheters while minimizing blood loss. It is available in lengths of 40, 61, 71 or 82 cm. The introducer is packaged with a custom dilator and a 180 cm, 0.032", super stiff, market cleared guidewire (K935170). A side port with three-way stopcock allows blood aspiration, fluid infusion, and pressure monitoring. An integrated Tuohy Borst adaptor is designed to hold a guidewire or catheter in place. The steerable sheath features distal side holes to facilitate aspiration and minimize cavitation, and a stainless-steel ring for visualization under fluoroscopy.

The handle is equipped with two linked rotating dials used to deflect the tip clockwise and counterclockwise 180°. The descriptions of the model numbers are listed below.

Model	Curve Length	Working Length (cm)	BRK Compatibility (cm)	9Fr Dilator Usable Length (cm)
TAL3085-001	Small (17mm)	40	N/A	61.7
TAL3085-002	Medium (22.5mm)	40	N/A	61.7
TAL3085-003	Large (50mm)	40	N/A	61.7
TAL3085-004	Small (17mm)	61	89	82.7
TAL3085-005	Medium (22.5mm)	61	89	82.7
TAL3085-006	Large (50mm)	61	89	82.7
TAL3085-007	Small (17mm)	71	98	92.7
TAL3085-008	Medium (22.5mm)	71	98	92.7
TAL3085-009	Large (50mm)	71	98	92.7
TAL3085-010	Small (17mm)	82	N/A	103.7
TAL3085-011	Medium (22.5mm)	82	N/A	103.7
TAL3085-012	Large (50mm)	82	N/A	103.7

The CardioCurve Steerable Sheath shaft is made from barium loaded Pebax and Nylon and includes a radiopaque tip marker for visibility under fluoroscopy and is braided, except for the distal tip, for kink resistance; the handle is made of ABS. The dilator is made of HDPE that is barium loaded for visibility under fluoroscopy

The CardioCurve Steerable Sheath Dilator can be used with a curved transseptal St. Jude Medical BRK™ type needle with stylet if indicated on the package label.

INTENDED USE/INDICATION FOR USE:

The Talon Surgical CardioCurve™ Steerable Sheath is indicated when introducing various cardiovascular devices to the epicardial or endocardial surfaces of the heart, including the left side of the heart through the interatrial septum.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

Technologically the CardioCurve Steerable Sheath is substantially equivalent to Agilis NxT Steerable Introducer, (K110450) in terms of design, materials, technology and performance.

The CardioCurve Steerable Introducer uses the same technology and has the same intended use, fundamental technology and performance as the predicate device and the reference devices. Technological differences are for physician convenience

Characteristic	CardioCurve Steerable Introducer (Subject Device)	Agilis NxT Steerable Introducer (K110450) (Predicate)	Substantial Equivalence Discussion
Intended Use	To provide access to the heart for use of cardiovascular devices.	Identical	N/A, Identical
Indications for use	The Talon Surgical CardioCurve Steerable Sheath is indicated when introducing various cardiovascular devices to the epicardial or endocardial surfaces of the heart, including the left side of the heart through the interatrial septum.	Similar The reference device includes the indication for epicardial access.	The subject device is substantially equivalent to the predicate device and identical to the reference device indications.
Technology			
Dimensions	Sheath ID = 8.5F (2.9mm)	Sheath ID =8.5F (2.8mm)	The slightly larger ID has no effect on which devices can pass through

Characteristic	CardioCurve Steerable Introducer (Subject Device)	Agilis NxT Steerable Introducer (K110450) (Predicate)	Substantial Equivalence Discussion
	Dilator OD 9F (3mm) Working Lengths (cm) = 40, 61, 71 and 82 cm Guidewire compatible = 0.032”	Dilator OD 8.5 F Working Length = 82cm (reference device is 40 cm and 71 cm) Guidewire compatible = 0.032”	the sheath, the subject device is substantially equivalent to the predicate device as verified through bench testing. The larger dilator OD matches the ID of the sheath. Bench testing demonstrates the subject device has substantially equivalent insertion forces to the predicate device. Legally marketed reference devices include or bookend the sizes offered by the subject device, which have been verified to be substantially equivalent to the predicate and reference devices through bench testing. Guidewire compatibility is identical between the subject device and predicate device.
Curve Shape	Bi-directional 180°, small curl (17mm), medium curl (22.5mm), and large curl (50mm)	180° 1-direction, 90° 2nd direction medium curl (22.4 mm)	The additional curl sizes are similar to the reference device size curls. The difference in curl diameter of less than 1mm falls within typical manufacturing tolerances. Bench testing raised no new concerns of safety or efficacy. The bi-directional feature of the subject device is therefore substantially

Characteristic	CardioCurve Steerable Introducer (Subject Device)	Agilis NxT Steerable Introducer (K110450) (Predicate)	Substantial Equivalence Discussion
			equivalent to the predicate and reference devices.
Tip	Atraumatic with marker bands	Identical	N/A, identical
Shaft	Polymer shaft with stainless steel braid reinforcement and deflection wires.	Identical	N/A, identical
Design	Hemostasis valve Sideport with 3-way stopcock Tuohy Borst	Identical Identical N/A	N/A, identical N/A, identical The addition of the Touhy Borst to the subject device does not affect the safety or efficacy of the device, as verified through bench testing, therefore the subject device is substantially equivalent to the predicate device.
Packaging	Card mounted inserted in a sterile barrier pouch and shelf box	PETG Tray inserted in a sterile barrier pouch and shelf box	Packaging testing has demonstrated that the subject device packaging configuration protects the device from damage and allows for sterile delivery of the product to the field, and is therefore substantially equivalent to the predicate device
Sterilization	Ethylene Oxide	Identical	N/A, identical

The CardioCurve Steerable Sheaths are substantially equivalent to the predicate device, Agilis NxT Steerable Introducer (K110450) and the reference devices, Agilis PF Delivery System (K111943) and Agilis NxT Introducer (K081645). The CardioCurve

Steerable Sheath and the Agilis Introducers provide access to the heart for the use of cardiovascular devices. The additional length, ability to deflect 180º in both directions, the ability to deflect from two locations on the handle and the addition of the Tuohy Borst to hold guidewires or catheters in place provide additional flexibility for the physician and do not raise new questions of safety and effectiveness from the predicate.

PERFORMANC TESTING

The CardioCurve Steerable Sheath was thoroughly tested and verifies that it performs as designed and is suitable for its intended use.

Performance Testing included the following:

- Visual Inspection
- Dimensions
- Guidewire Compatibility
- Dilator Compatibility
- Deflection and retention
- Shaft tip buckle
- Air and liquid leakage per ISO 11070:2017
- Hub compatibility with ISO 80369-7
- Stopcock compliance per ISO 594
- Tensile Strength per ISO 11070
- Distribution and Packaging Tests per ASTM D4169:2016 and ISO 11607-1
- Packaging Aging per ASTM F1980,
    - Visual per F1886-98
    - Dye Leak per ASTM F 2096-11
    - Seal Strength per ASTM F88/F88M-15,

Biocompatibility per ISO 10993-1 for an external communicating device, limited (<24 hour) blood contacting device.

- Cytotoxicity: MEM Extraction Cytotoxicity Assay per 10993-5
- Sensitization: Guinea Pig Maximization Test per 10993-10
- Irritation: Intracutaneous Reactivity Test per 10993-10
- Toxicity: Materials Mediated Rabbit Pyrogen Test SO 10993-11
- Toxicity: Acute Systemic Toxicity per SO 10993-11
- Hemocompatibility: ASTM Hemolysis Assay: Direct and Extract Methods per 10993-4
- Hemocompatibility: Complement Activation Assay – C3a and SC5b-9 Methods per 10993-4
- Hemocompatibility: Partial Thromboplastin Tine (PTT) Assay per 10993-4:2017
- Thrombogenicity Study in Ovine Model per 10993-4:2017

All testing met the requirements and passed. There are no new questions raised regarding safety or efficacy of the CardioCurve Steerable Sheath.

CONCLUSIONS

The CardioCurve Steerable Sheath is substantially equivalent to the predicate device.