



February 27, 2017

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Rhythm Xience, Inc.
c/o Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K170373
Trade/Device Name: Flextra Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: February 4, 2017
Received: February 7, 2017

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light blue, semi-transparent "FDA" watermark.

for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

Device Name

FLEXTRA™ STEERABLE INTRODUCER

Indications for Use (Describe)

The Flextra™ Steerable Introducer is indicated for introducing various cardiovascular catheters into 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.

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5.0 510(k) SUMMARY AS REQUIRED BY 21CFR 807.92

510(k) Number: K170373 or TBD [X]

Date Prepared: January 24, 2017

Table 5.1 Submitter Information

Submitter: Rhythm Xience, Inc. Street Address: 10025 Valley View Road Suite 130 Eden Prairie, MN 55344 Establishment registration: awaiting 510(k) clearance prior to initial registration/listing	Contact Person: Jim Hassett Phone: 952-479-7903 Email: jimhassett@rhythm-xience.com
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Table 5.2 Device Information

Trade Name	Flextra Steerable Introducer
Common Name	Catheter Introducer
Classification Name	Introducer, Catheter
Regulation /Product Code	21 CFR 870.1340
Product Code	DYB
Regulatory Classification:	Class II
Device Panel:	Cardiovascular

The RXI Flextra Steerable Introducer is substantially equivalent to the previously cleared predicate, St. Jude Medical (SJM) Agilis™ NxT Steerable Introducer, K061363.

Table 5.3 Predicate Device

Predicate Device	Manufacturer	FDA 510(k)
Agilis™ NxT Steerable Introducer	St. Jude Medical, Inc.	K061363

5.1 Device Description

The Flextra Steerable Introducer set contains a steerable introducer, integrated vessel dilator/transseptal needle (component branded as Lancer™), guidewire, and ECG adapter cable. The set is designed to facilitate vascular access to the heart and then provide variable catheter positioning within the cardiac anatomy (see **Figure 5.1**).

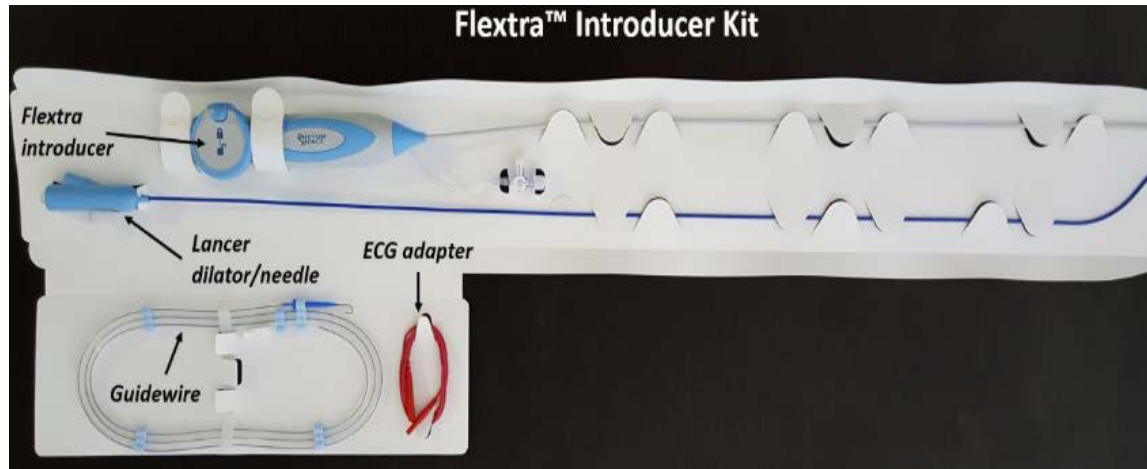


Figure 5.1 Flextra Steerable Introducer Set

The Flextra introducer is an elongated shaft with central lumen capable of accepting the Lancer dilator/needle as well as various cardiac catheters. The shaft has a proximal handle with a rotating actuator that allows the user to change the degree of curvature on the distal tip of the shaft (referred to as steerable tip, deflectable tip, or dynamic tip). Rotating the actuator can deflect the tip, in a planar fashion, $\pm 180^\circ$. The handle is also fitted with a hemostasis valve to minimize blood loss during catheter introduction, and/or exchange, as well as a sideport with 3-way stopcock to allow blood aspiration, fluid infusion, and pressure monitoring. The introducer shaft features distal side holes to facilitate aspiration and prevent cavitation plus an embedded platinum radiopaque tip marker to facilitate fluoroscopic visualization. (See **Figures 5.2-5.3**)

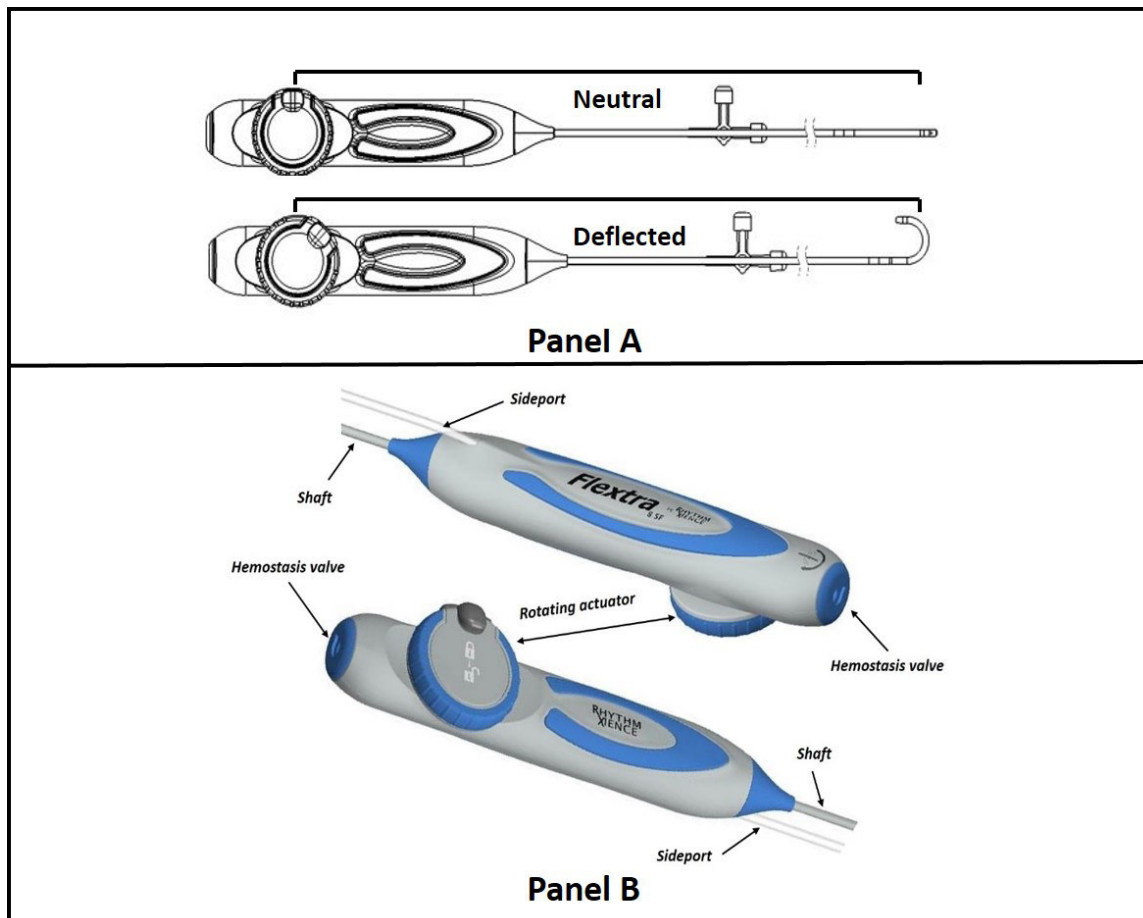


Figure 5.2 Panel A is profile technical drawing depicting the tip response to actuator rotation. Panel B illustrates the handle features.

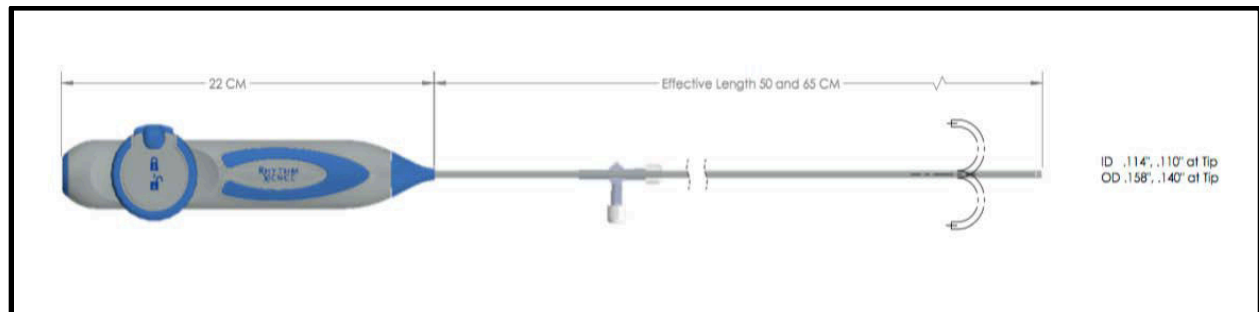


Figure 5.3 Flextra Steerable Introducer Dimensional Specifications

The set includes the following accessories (see **Figure 5.4**):

- Lancer™ Integrated Dilator/Needle
- J-Tip Guidewire
- ECG Adaptor

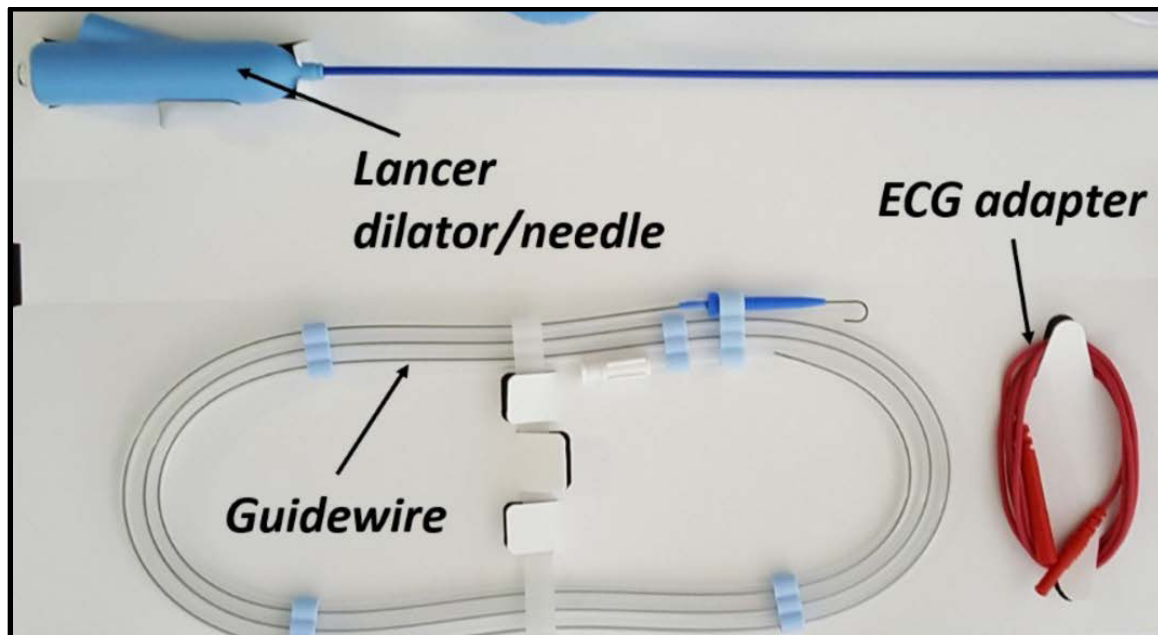


Figure 5.4 Flextra Steerable Introducer Accessories

The Lancer integrated dilator/needle combines the dilator and transseptal needle into a single component (see **Figures 5.5 – 5.7**). The needle is used to puncture the interatrial septum to gain access to the left atrium similar to the St. Jude Medical BRK™ Transseptal Needle (K072278). The Lancer consists of an elongated shaft with a tapered tip and central lumen to track over a guidewire in a similar fashion to conventional dilators. The lumen of the Lancer is fitted with a hollow stainless steel transseptal needle and both the shaft and needle are connected to the same proximal handle. The needle lumen will accept guidewire sizes up to 0.032 inches in diameter. Inside the Lancer handle, the needle is affixed to a spring-tensioned actuator that prevents needle extension until the operator purposely advances the needle via a slider button located on the outer surface of the handle. The proximal handle is fitted with a Luer connector to gain access to the central lumen of the needle. The handle is also fitted with an electrical connector to monitor an ECG from the needle while in the heart, utilizing the ECG adapter cable. This is done in a similar manner as pericardiocentesis kits whereby electrocardiograms are monitored from the needle during use (reference **Figure 5.8**, Boston Scientific PeriVac Pericardiocentesis Kit, K032050).

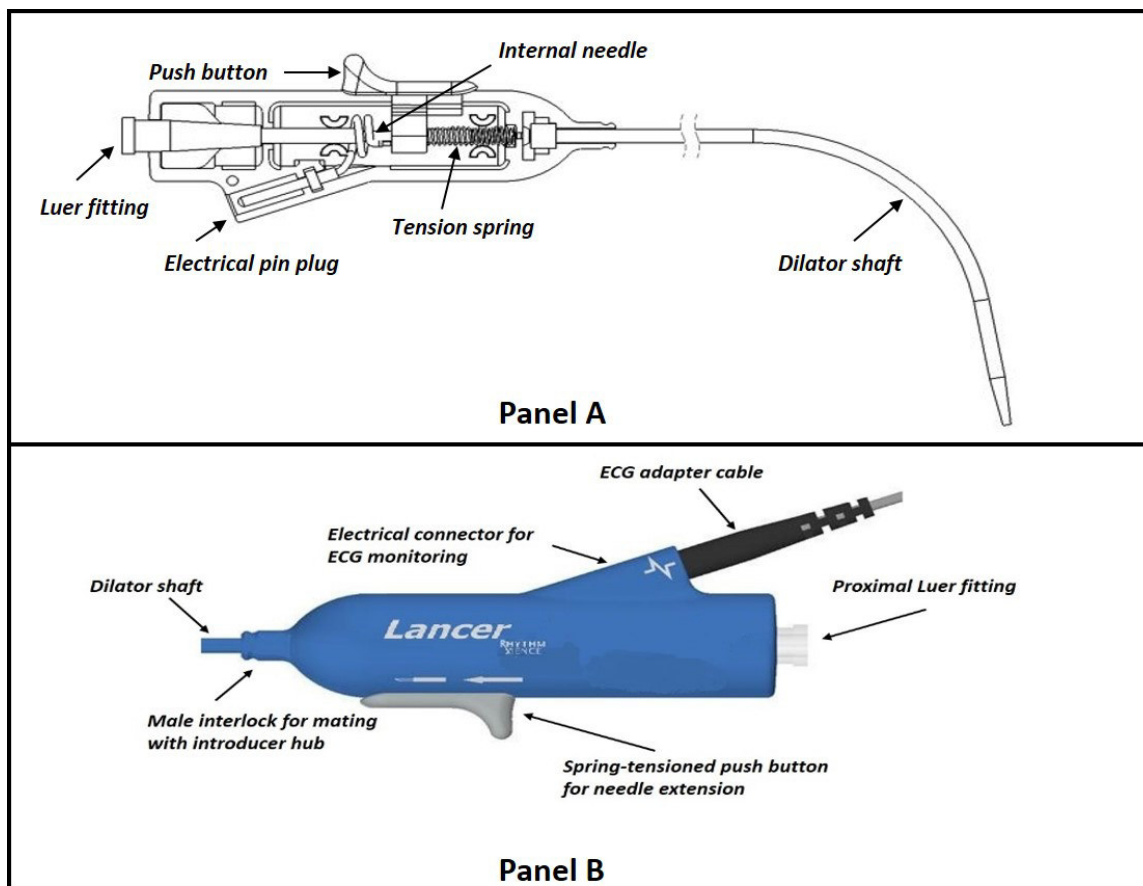


Figure 5.5 Lancer™ integrated dilator/needle. **Panel A** is a profile technical drawing depicting the internal components of the handle. **Panel B** illustrates the handle features.

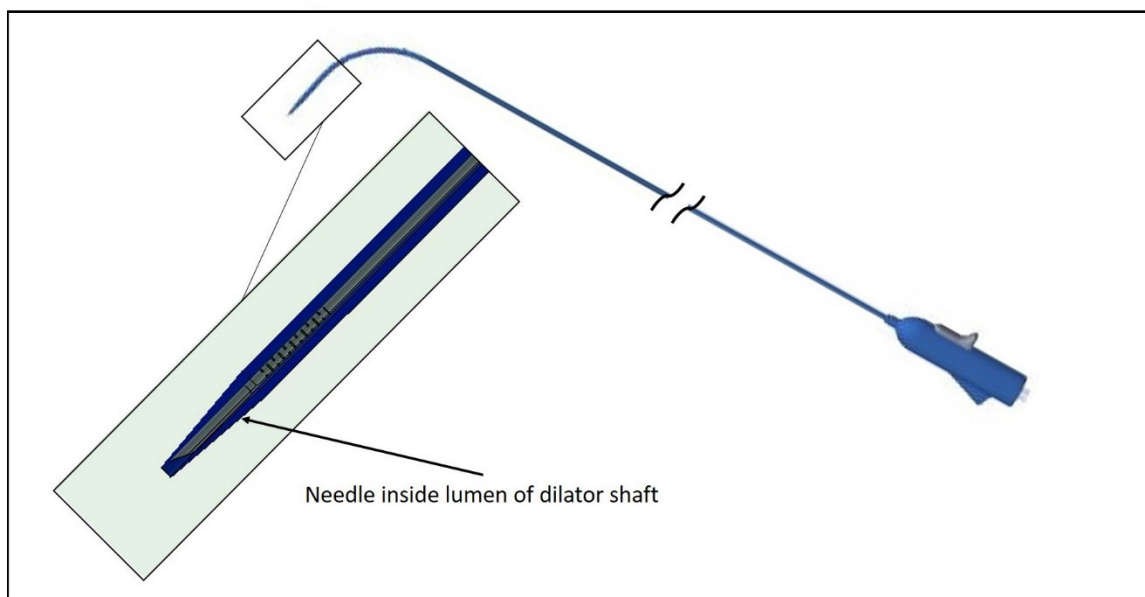


Figure 5.6 Lancer™ with inset depicting internal needle in baseline retracted position

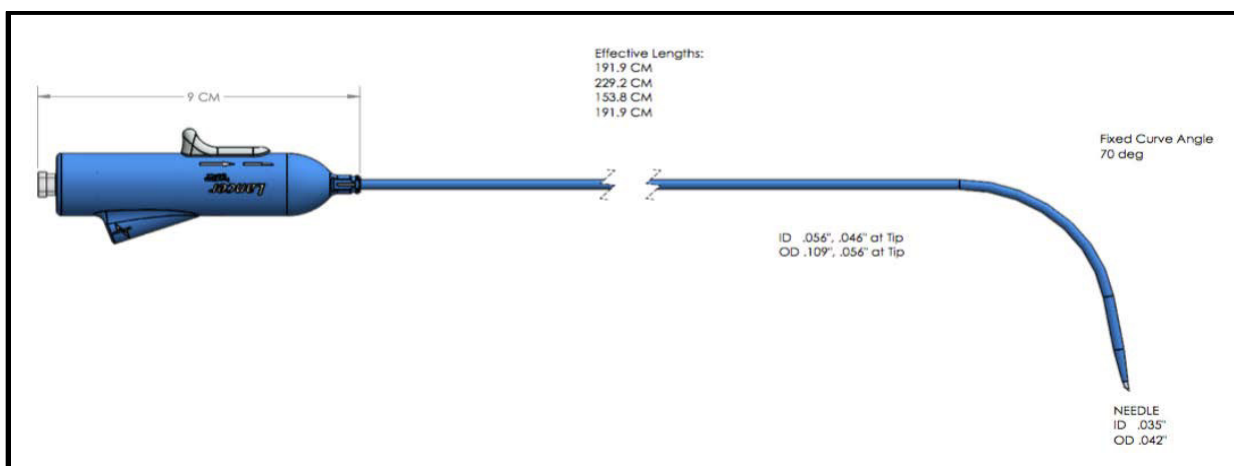


Figure 5.7 Lancer dimensional specifications

The distal end of the Lancer handle and the proximal end of the Flextra handle are designed with male/female surfaces to mate the components together into a snap-fit closure (see **Figures 5.9 - 5.10**).



Figure 5.9 Flextra and Lancer Mating Side-view

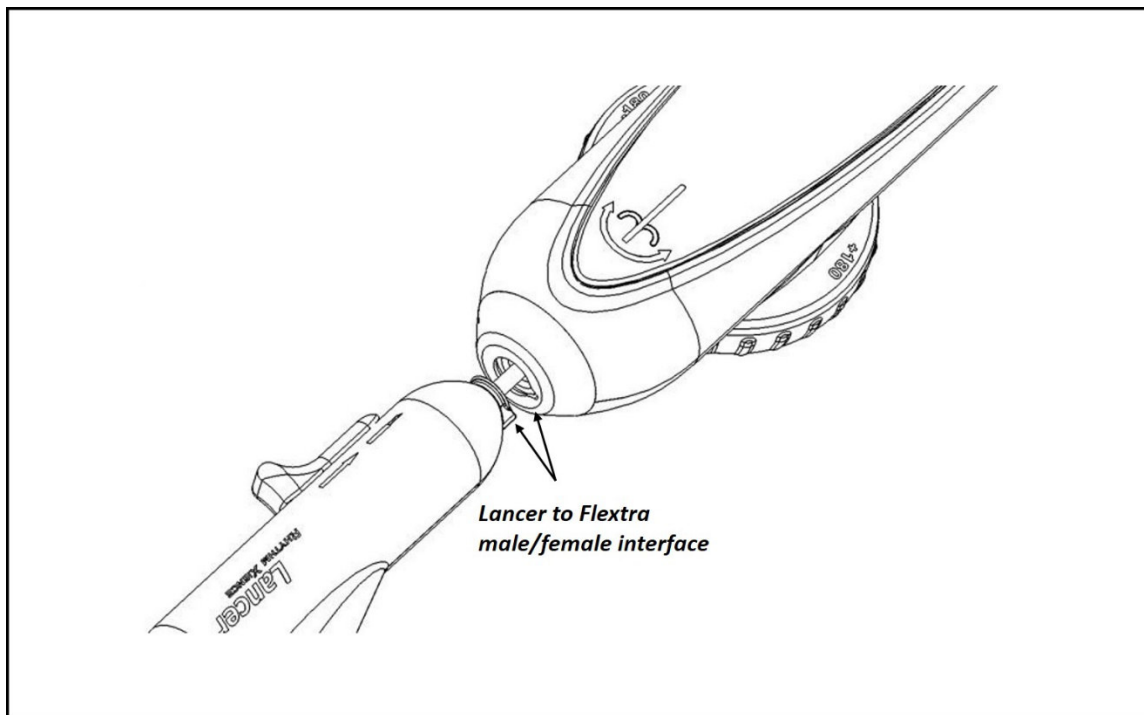


Figure 5.10 Flextra and Lancer Snap-fit Closure Mating Feature

The guidewire included in the kit is manufactured by Lake Region Medical (K935170) and is supplied in a polypropylene retainer coil with a J-straightener and Luer fitting. The Luer fitting is compliant to ISO 594-1 and ISO 594-2. The ECG adapter cable included is manufactured by Bioconnect (RF Industries, Inc.), is one (1) meter long, and has male/female DIN 0.080 inch touch-proof connectors on the ends.

The patient-contacting materials used in the Flextra Steerable Introducer set are listed in **Table 5.4**. A detailed listing of all materials used in the set is provided in this submission.

Table 5.4 Flextra Steerable Introducer List of Materials

Component	Materials
Flextra Steerable Introducer	
Shaft	Pebax (63D, 55D, 35D) and Vestamid with Barium Sulfate and gray colorant Polytetrafluoroethylene (PTFE) Polyethylene terephthalate Ethyl Cyanoacrylate Siloxane Lubricant (Nusil MED-4162) Platinum
Sideport	Polycarbonate, High Density Polyethylene (HDPE) Polyvinyl Chloride (PVC) UV Adhesive
Hemostasis Valve Assembly	Polyisoprene Buna-N, Durometer Shore A50 304 Stainless Steel Acrylonitrile butadiene styrene (ABS) with white colorant Acrylic UV Curable Silicone, Nusil Med-420 Ethyl Cyanoacrylate
Lancer Dilator/Needle	
Shaft	Polyethylene Hexene Copolymer Ethylene Homopolymer Barium Sulfate with blue colorant
Hypotube	304 Stainless Steel
Needle	304 Stainless Steel
Luer fitting	Polycarbonate
Guidewire	
Guidewire	Polytetrafluoroethylene (PTFE) coated stainless steel

There are two (2) models of the Flextra Steerable Introducer set based on useable length (the Lancer component is length-matched to the Flextra introducer). All have an inner diameter of 8.5 French. These include:

1. Medium Curl, 50 cm, 8.5 French
2. Medium Curl, 65 cm, 8.5 French

5.2 Indications for Use

The Flextra Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

5.3 Summary of Testing

The Flextra Steerable Introducer set underwent the tests listed in **Table 5.5**. Testing was conducted at three different time intervals: 1) Baseline – 2x sterilization, environmental conditioning and distribution simulation (T=0); 2) Accelerated aging – 2x sterilization and 12-month accelerated aging (T=12aa); and 3) Real-time aging – 2x sterilization and 12-month real-time aging (T=12rt). The testing was performed by the following vendors and locations:

- Biocompatibility testing and an Animal Study were performed at American Preclinical Services, LLC., (APS) located in Minneapolis, MN.
- Sterilization testing was performed by Steris Isomedix, located in Minneapolis, MN.
- Environmental Conditioning, Distribution Simulation Testing, Accelerated Aging, Peel Strength and Bubble Leak Testing were performed by Distribution Dynamic Labs, Inc (DDL), Eden Prairie, MN.
- Particulate testing was performed at Nelson Labs located in Salt Lake City, UT.
- Electrical testing was performed at Medical Equipment Compliance Associates, LLC (MECA) located in Franklin, WI.
- All other tests were performed by CRI-Devices, Maple Grove, MN.

Table 5.5 Summary of Testing

Test Type	Test Name
Biocompatibility	Hemocompatibility Cytotoxicity Sensitization Irritation Pyrogenicity Systemic Toxicity Thrombogenicity
Sterilization Validation	LAL Bioburden EO residuals
Packaging	Environmental Conditioning Distribution Simulation –Post Environmental Conditioning/ Visual Evaluation - Post Environmental Conditioning/ Distribution Simulation Bubble Test - Post Environmental Conditioning/ Distribution Simulation/ Visual Evaluation Seal Strength- Post Environmental Conditioning/ Distribution Simulation/ Visual Evaluation/ Bubble Leak
Shelf Life	12 Month Accelerated Aging 12 Month Real Time Aging
Inspection	Corrosion Resistance Surface Inspection Tip Deflection

Test Type	Test Name
	Tip Curve Retention Dimensional Verification
Functional Testing	Pushability/Trackability Sheath Compatibility (Insertion/Withdrawal Force) System Leak (Hemostasis, Luer, Aspiration) Coating Integrity (Particulate, Friction) Radiopacity Needle Actuation Electrical Continuity Pin-Needle
Mechanical	Kink Resistance Torque Resistance Tip/Marker band Tensile Sheath to Hemostasis Valve Tensile Shaft to Handle Tensile Needle to Button Tensile Luer to Hypo. Tensile Flushing Tubing to Stopcock Tensile Flushing Tubing to Hemostasis Valve Tensile
Electrical	Electrical Safety IEC 60601
Animal Study Comparing to Predicate Device	Access from packaging Visual Inspection Preparation Preliminary Device Function Advancement of Guidewire to Superior Vena Cava Fluoroscopic Visualization Intracardiac Echocardiographic Visualization Fossa Ovalis Localization Maintenance of component orientation ECG Monitoring Fossa Ovalis Puncture Needle Lumen Function Dilator Crossing of Fossa Ovalis Sheath Crossing of Fossa Ovalis Removal of Device Overall Performance Device Function -Aspirate, Flush, Transduce and Deflect

5.3.1 Biocompatibility

The Flextra Steerable Introducer underwent the following biocompatibility tests as shown in **Table 5.6**. All testing completed passed with the results listed.

Table 5.6 Biocompatibility Testing Summary

Test type	Test name	Result
Hemocompatibility	Hemolysis Test; ASTM F756 Method; Direct Contact and Extract Contact	Pass, Non- Hemolytic
	Complement Activation; C3a Assay and SC5b-9 Assay	Pass, Non-Reactive
	Platelet and Leukocyte	Pass
	Partial Thromboplastin Time (PTT)	Pass, Non-Activator
	Prothrombin Time Assay (PT)	Pass
Cytotoxicity	MEM Elution: L-929 Mouse Fibroblast Cells	Pass, Non-Cytotoxic
Sensitization	Guinea Pig Maximization (2 extracts)	Pass, Non-Sensitizer
Irritation	Intracutaneous Reactivity Test (2 extracts)	Pass, Non-Irritant
Pyrogen	Materials Mediated Pyrogenicity Test	Pass, Non- Pyrogenic
Systemic Toxicity	Acute Systemic Toxicity Test (Aqueous and Non-Aqueous Extract)	Pass, Non-Toxic
<i>In vivo</i> thrombogenicity	4-hour Thrombogenicity; 2 canines, Flextra and Lancer separately	Pass, Non-Thrombogenic

Results

The Flextra Steerable Introducer passed all biocompatibility testing. The full protocols and results for each test are contained in the submission.

5.3.2 Sterilization

The Flextra Steerable Introducer will be offered as sterile to a 10^{-6} sterility assurance level (SAL) by an ethylene oxide (EO) sterilization process. The device will undergo EO sterilization at STERIS Isomedix, located at 380 90th Ave NW, Minneapolis, MN 55433. The sterilization protocol provided by STERIS Isomedix establishes the procedures for validation of an ethylene oxide sterilization process for this device. The performance qualifications were executed using the overkill approach as referenced in the international standard, ANSI/AAMI/ISO 11135.

The following tests are conducted to assess the product sterilization:

- Biological Indicator Population Enumeration Testing
- Bioburden Testing
- Product Sterility Testing
- Bacteriostasis/Fungistasis Testing
- Biological Indicator Sterility Testing
- EO Residuals Testing

Results

The Flextra Steerable Introducer is pending sterilization validation. The protocol is contained in the submission.

5.3.3 Packaging

The Flextra Steerable Introducer sets are situated on a thermoformed high-density polyethylene (HDPE) backer card and are shipped sterile in a sealed Tyvek® pouch placed inside a cardboard shelf box and labeled as single use only. The devices underwent the following distribution and packaging testing:

- Environmental Conditioning
- Distribution Simulation
- Dimensional/Visual Inspection
- Package Integrity/Bubble Test
- Package Integrity/Peel Strength

Prior to the testing, all samples had undergone 2x EO sterilization cycles at STERIS Isomedix. The sterilized units were packaged into shippers. The units/shippers were subjected to environmental conditioning followed by the distribution simulation per ASTM D 4169-09, Distributions Cycle 13; Assurance Level II, and thermal conditioning per ISTA 2A (2011). Testing was performed by Distribution Dynamic Labs, Inc. (DDL, Inc.) located at 10200 Valley View Road, Eden Prairie, MN 55344.

Results

The Flextra Steerable Introducer passed all distribution and packaging testing. The full protocols and results are contained in the submission.

5.3.4 Shelf Life

The Flextra Steerable Introducer will be labeled with a 12-month shelf life. The device was subjected to 12-month accelerated aging and 12 -month real-time aging (on-going at time of submission). The test devices were subjected to accelerated aging environmental conditions of 55°C ± 2°C and <20% RH for 38 days to simulate the equivalent of 12 months of real-time aging as guided by ASTM F 1980-07 (2011). The Flextra Steerable Introducer passed all baseline and accelerated aging testing while maintaining its sterile barrier.

5.3.5 Performance Testing

Mechanical and functional testing of the Flextra Steerable Introducer with associated Lancer Integrated Dilator/Transseptal Needle, and associated kit accessories including the guidewire and

ECG extension lead wire, were tested post-sterilization: immediately after manufacturing (t=0), after twelve months accelerated aging (t=12aa). Test samples have been manufactured and reserved for testing after twelve months of real-time aging has occurred (t=12rt).

Tests include:

- Product Inspection/Dimensional Verification
- Surface Inspection
- Label Legibility
- Label Adhesion
- Sheath Compatibility (Insertion/Withdrawal)
- Pushability/Trackability
- Tip Deflection
- Tip Curve Retention
- System Leak -Liquid Leak and Hemostasis
- System Leak – Luer
- System Leak – Aspiration
- Coating Integrity / Particulate Evaluation
- Coating Integrity / Friction Reduction
- Kink Resistance
- Torque Resistance
- Tip / Markerband Tensile
- Sheath to Hemostasis Valve Tensile
- Shaft to Handle Tensile
- Needle to Button Tensile
- Luer to Hypotube Tensile
- Needle Actuation
- Flush Tubing to Stopcock Tensile
- Flush Tubing to Hemostasis Valve Tensile
- Electrical Safety
- Electrical Continuity Pin-Needle
- Corrosion Resistance
- Package Integrity – Bubble Leak
- Package Integrity – Peel Strength
- Radiopacity

Results

All protocol requirements/specifications were met. The full protocols and results for each test are contained in the submission.

5.3.6 Animal Study

As part of Design Validation, animal testing was performed at American Preclinical Services, Inc. (APS), located in Minneapolis, MN. APS is USDA registered to conduct research in animals and is AAALAC accredited. All testing followed the requirements for Good Laboratory Practices per 21 CFR 58 as well as ISO 10993 for Biologic Evaluation of Medical Devices.

A single animal study was performed that combined the evaluation of another device that is being submitted under a separate file by RXI. This was decided due to ethical concerns to limit the number of animals required. This study compared the Flextra Steerable Introducer device to the predicate device listed in **Table 5.3**.

Results

This study indicates that the Flextra Steerable Introducer performed for the selected parameters substantially equivalent to the commercially available SJM Agilis NxT Steerable Catheter Introducer (K061363). The full report and results are included in the submission.

5.4 Comparison to the Predicate Device

The Flextra Steerable Introducer and St. Jude Agilis NxT are made with similar medical-grade polymers and internal mechanical componentry. Both have a rotating actuator on the proximal handle that causes deflection of the distal tip. The handles of each also contain a hemostasis valve and sideport tube with stopcock. Each set also includes a vessel dilator and guidewire to facilitate introduction into the vasculature and advancement to the heart.

In order to gain transseptal access to the left side of the heart, the Agilis NxT requires the use of a separate transseptal needle.

The primary difference with the Flextra is that the needle is integrated into the vessel dilator for convenience. Feature benefits of this integrated dilator/needle include proper alignment of components when assembled, length-matched needle, automatic needle tip retraction within dilator, and the ability to obtain an electrogram from the needle via an ECG adapter. Each of these functions must be performed manually with the Agilis NxT device.

These differences provide convenience and efficiency over the predicate device and do not impact the intended use.

5.5 Summary of Standards Utilized in Testing

The standards used in the testing of the device are outlined in **Table 5.7**.

Table 5.7 Standards Utilized

	Standards No.	Standards Organization	Standards Title	Version
1	10993-1	ISO	Biological Evaluation of Medical Devices	2009
2	11135-1	ISO	Sterilization of health care products – Ethylene oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices	2014
3	10555-1	ISO	Sterile, Single-Use Intravascular Catheters	2013
4	F2096-11	ASTM	Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Leak)	2014
5	D4169-14	ASTM	Performance Testing of Shipping Containers and Systems Distribution Simulation Testing	2014
6	F756-13	ASTM	Standard Practice for Assessment of Hemolytic Properties of Materials	2013
7	60601-1:2005/(R)2012 and A1:2012	AAMI/ANSI ES	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	2012
8	11607-1	ISO	Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems	2006
9	11607-2	ISO	Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes	2006
10	14971	ISO	Medical Device: Application of Risk Management	2012
11	594-1	ISO	Conical fittings with 6% (Luer) taper- Part 1: General requirements	1986
12	594-2	ISO	Conical fittings with 6% (Luer) taper- Part 2: Lock Fittings	1998
13	F88/F88M-15	ASTM	Standard Test Method for Seal Strength of Flexible Barrier Materials	2009
14	F2394-07(2013)	ASTM	Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System	2013
15	F2888-13	ASTM	Standard Test Method for Platelet Leukocyte Count	2013

	Standards No.	Standards Organization	Standards Title	Version
16	11135-1:2007	ISO	Sterilization of Healthcare products – Ethylene oxide – Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices.	2007
17	14:2009	AAMI TIR	Contract Sterilization Using Ethylene Oxide	2009
18	16:2009(R)2013	AAMI TIR	Microbiological Aspects of Ethylene Oxide Sterilization	2013
19	11135-2:2008	ISO	Sterilization of Healthcare Products – Ethylene Oxide – Part 2: Guidance on the Application of ISO 11135-1	2008
20	10993-7:2008(R)2012	ISO	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	2012
21	10993-04:2002(R)2013	ISO	Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interaction with Blood	2013
22	10993-05:2009 (R)2014	ISO	Biological Evaluation of Medical Devices - Part 5 Tests for In Vitro Cytotoxicity	2014
23	10993-11:2006(R)2010	ISO	Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity	2010
24	10993-12	ISO	Biological Evaluation of Medical Devices - Part 12: Sample Preparation and Reference Materials	2012
25	10993-10	ISO	Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization	2012
26	13485:2016	ISO	Medical Devices --Quality Management System—Requirements for Regulatory Purposes	2016
27	F2382-04	ASTM	Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT)	2010
28	11070:2014	ISO	Sterile Single-use Intravascular Introducers, Dilators and Guidewires	2014
29	F1980-07	ASTM	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	2011
30	F640-12	ASTM	Standard Test Methods for Determining Radiopacity for Medical Use	2012
31	2A	ISTA	Packaged Products 150lbs or less	2011
32	60601-1-2	IEC	Medical electrical equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	2014

	Standards No.	Standards Organization	Standards Title	Version
33	10555-5	ISO	Intravascular Catheters-Sterile, single-use intravascular catheters- Part 5: Over Needle Peripheral Catheters	2013
34	ST72:2011	ANSI/AAMI	Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing	2011
35	33	USP	Transfusion and Infusion Assemblies and Similar medical devices	2010
36	F1886	ASTM	Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	2016
37	15223-1	ISO	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements	2016

5.6 Conclusions

The Flextra Steerable Introducer has similar design, materials, and technical requirements as the predicate device. The Flextra Steerable Introducer performs as intended, and presents no unacceptable risks to the intended patient population or end user.

The conclusion drawn from the nonclinical tests, summarized in this submission, demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate device listed in **Table 5.3**.

The Flextra Steerable Introducer is substantially equivalent to the predicate device, the SJM Agilis NxT Steerable Catheter Introducer (K061363).