



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 24, 2016

Cardiofocus, Inc.
Seema Paliwal
Regulatory Affairs Specialist II
500 Nickerson Road
Suite 500-200
Marlborough, Massachusetts 01752

Re: K152310
Trade/Device Name: HeartLight Deflectable Sheath
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: Class II
Product Code: DRA, DYB
Dated: February 17, 2016
Received: February 18, 2016

Dear Seema Paliwal:

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

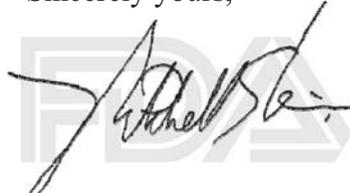
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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 yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

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)

K152310

Device Name

HeartLight® Deflectable Sheath

Indications for Use (Describe)

The CardioFocus Deflectable Sheath is indicated for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.

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 - K152310

5.1 General Information:

Date Summary Prepared:	February 17, 2016
Applicant:	CardioFocus Inc. 500 Nickerson Road Marlborough, MA 01752 Telephone: (508) 658-7200 Fax: (508) 480-0600
Establishment Registration No.:	1225698
Contact Person:	Seema Paliwal, PhD, RAC Regulatory Affairs Specialist II Telephone (direct dial): (508) 658-7208 Fax: (508) 480-0600 Email: spaliwal@cardiofocus.com
Trade Name:	HeartLight® Deflectable Sheath
Common Name:	Steerable Sheath and Dilator
Classification Name:	Steerable Catheter
Classification & Panel:	Class II, 21 CFR § 870.1280, Cardiovascular
Product Code:	DRA, DYB
Predicate Device(s):	FlexCath® Advance™ Steerable Sheath & Dilator, Model 4FC12 (K123591)
Reference Device(s):	HeartSpan® Steerable Introducer, Models FST-085-00 FST-085-01 and FST-085-02 (K132164)

5.2 Device Description

The HeartLight® Deflectable Sheath is a sterile, disposable device which provides a conduit for catheter introduction into the vasculature and into the chambers of the heart. The Deflectable Sheath is able to move its distal section in one direction in a single plane and is activated by a rotating knob at the front of the device handle. The deflection of the sheath and the torquing of the device allow the distal end of the sheath to be positioned at the ostium of pulmonary veins.

The Deflectable Sheath is comprised of the following basic elements and features:

- A radio-opaque flexible shaft, 12F ID and 16F OD, having a distal section which is deflectable by means of a wire connected to a mechanism in the handle. The shaft is hollow, comprised of a central lumen through which a catheter or a dilator is able to pass.
- A handle providing a means to torque, deflect and axially position the sheath. Deflection is accomplished by twisting a knob at the distal end of the handle.
- A hemostasis valve located at the proximal end of the central lumen and the handle forms a seal with an inserted object such as a catheter or a guidewire.
- A side port and stopcock connected to the hemostasis valve to permit evacuation of air inside the sheath and to permit constant irrigation of the sheath during use.
- Vent holes located within the soft distal tip allow purging of the sheath when the end of the sheath is pressed against tissue.
- A dilator that is matched to the sheath to provide a smooth transition from a guide wire to the outside diameter of the distal tip of the sheath. The dilator's hub has a lock feature to allow the dilator to be axially locked in relation to the sheath's handle when desired.
- A radio-opaque marker at the distal tip.

This device is intended to be used within a hospital or medical facility only by physicians trained in standard transeptal techniques and familiar with angiography and electrophysiology catheters and delivery systems.

5.3 Intended Use

Facilitates introducing various cardiovascular catheters into the heart.

5.4 Indications for Use

The HeartLight® Deflectable Sheath is indicated for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.

The new device has identical indications for use as the predicate device, FlexCath® Advance™ Steerable Sheath. Both, the new device and the predicate device are intended for introducing and positioning catheters to reach the superior and inferior pulmonary veins of the heart and thus have clinically equivalent therapeutic use.

The reference device, HeartSpan® Steerable Introducer from Merit Medical is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. The CardioFocus sheath has similar indications for use as the reference device.

5.4.1 Comparison to the Predicate Device

The CardioFocus Deflectable Sheath is compared to the currently marketed predicate device FlexCath Advance™ Steerable Sheath (K123591) in the following table:



Element of Comparison	FlexCath® Advance™ Steerable Sheath (K123591) (Predicate device)	HeartLight® Deflectable Sheath (K152310) (New Device)
Intended Use/ Indications for Use		
Intended Use	Facilitates introducing various cardiovascular catheters into the heart.	Facilitates introducing various cardiovascular catheters into the heart.
Indications for Use	The FlexCath Advance Steerable Sheath is intended for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.	The CardioFocus Deflectable Sheath is indicated for percutaneous catheter introduction into the vasculature and into the chambers of the heart. The sheath deflection facilitates catheter positioning.
Sterility, Shelf Life		
Usage	Single use and disposable	Same
Sterilization Method	Sterilized with ethylene oxide.	Same
Shelf Life	2 years	Same
Storage Conditions	Store in a cool, dark, dry place.	Same
Performance/ Technology/Design		
Steerable sheath improves access to hard-to-reach anatomy	Yes	Same
Radiopaque for visualization under fluoroscopy - Radiopaque tip marker for enhanced fluoro visibility	Yes	Same
Uni-directional curve deflection	Yes ≥ 135°	Similar ≥ 130° The deflection angle provides maneuverability to the catheters that advance through the sheath for access to the chambers of the heart. The difference in deflection angle is minimal and does not affect the safety and effectiveness of the new device relative to the predicate device. Bench testing of the sheath supports the device design.
Hemostasis valve to prevent blood leakage and or air ingress	Yes	Same
Ergonomic handle to provide comfort	Yes	Same

Element of Comparison	FlexCath® Advance™ Steerable Sheath (K123591) (Predicate device)	HeartLight® Deflectable Sheath (K152310) (New Device)
Soft, atraumatic tip to minimize the likelihood of perforation or damage to atrial or venous tissue.	Yes	Same
Braided shaft provides exceptional torquability, pushability, and kink resistance	Yes	Same
Sideport for infusion and contrast injection	Yes	Same
Usable Length	65 cm	75 cm Different from predicate. Usable length of the sheath provides greater accessibility. The shaft usable length should be long enough to place 13 cm of sheath into the chambers of the heart. Bench testing of the sheath supports the device design.
Inner Diameter	12F	12F – Same
Dilator to Guide wire Compatibility	Accepts up to 0.035” guidewire	Accepts 0.035” or 0.038” guidewire Similar. Dilator to Guide wire compatibility defines the specification of guide wire accepted by the device. Bench testing of the sheath supports the device design.
Biocompatibility - The device may contact circulating blood or have indirect blood contact for up to 24 hours	Yes	Same nature and duration of bodily contact.
Materials		
Shaft Material	Pebax with Barium Sulfate, stainless steel braid and PTFE liner	Same. Stainless Steel Braid Reinforced Pebax with Barium Sulfate with Stainless Steel Pull-Wire, PTFE Lined
Hemostasis valve material	Silicone	Same
Hemostasis hub and cap material	Polycarbonate	Isoplast

Element of Comparison	FlexCath® Advance™ Steerable Sheath (K123591) (Predicate device)	HeartLight® Deflectable Sheath (K152310) (New Device)
		Similar. Biocompatibility testing of the sheath supports the device materials.
5Hemostasis valve	Polycarbonate	Same
Adhesive (shaft to hub-sheath valve assembly)	Cyanoacrylate	Same
Dilator shaft and hub material	Polyethylene	Polyethylene with BaSO4 Similar. Biocompatibility testing of the sheath supports the device materials.
Pouch material	Tyvek/nylon polyethylene pouch	Same

5.4.2 Technological Characteristics - Comparison of New Device to Predicate Device

The HeartLight Deflectable Sheath has the following similarities to the predicate device FlexCath Advance Steerable Sheath (K123591):

- Identical Intended Use/ Indications for Use
- Equivalent technological characteristics and basic sheath design - steerable and deflectable sheath for accessibility, radiopaque for visibility, ergonomic handle and braided shaft for functionality, hemostasis valve and soft tip for safety.
- Similar materials
- Same sterilization process and Shelf Life

The new device has minor differences from the predicate in the deflection angle, usable length, dilator to guide wire compatibility and material used on the dilator shaft and hub and hemostasis hub and cap.

The design verification and biocompatibility testing of the HeartLight Deflectable Sheath support the design, performance and use of the materials for their indications for use. The safety and effectiveness of the new device is not compromised relative to the predicate device.

5.5 Summary of Performance Data

Design Verification testing were performed for the HeartLight 12F Deflectable Sheath to verify that design outputs meet relevant performance and functional requirements and conforms to the intended use of the device.

Performance and functional requirements testing included:

12F Sheath and dilator size:

Sheath overall and free length, Sheath tube O.D., tip I.D., tip wall thickness, marker band location, Sheath side port diameter and location, Dilator free length.

12F Sheath functionality

Deflectable sheath testing for accessibility, radiopaque for visibility, ergonomic handle and braided shaft for functionality, hemostasis valve and soft tip for safety. The specific testing included:

- Sheath hemostasis and air leak resistance
- Sheath distal articulation stability, tip articulation max and min, bend radius, kink resistance
- Sheath functionality after foreseeable worst case use: constrained geometry, life cycle test, multiple insertions and retractions
- Sheath deflection and deflection stability
- Sheath handle actuation: torque required to articulate tip, functionality after handle overtorque
- Sheath injection pressure
- Sheath delamination of PTFE liner
- Catheter rotation test
- Packaging integrity
- Sheath side port joint integrity, Stopcock tubing kink specification

Shelf life testing

The 2 year accelerated shelf life design verification testing was performed to support 2 year shelf life of the 12F Deflectable Sheath. The test results passed the design verification and established a two year shelf life for the HeartLight® 12F Deflectable Sheath.

Sterilization Validation (Ethylene Oxide)

Biocompatibility Testing (Verification)

Biocompatibility tests for the 12F Deflectable sheath and the 12 Dilator were performed according to ISO 10993-1 for an external communicating device in contact with circulating blood for less than 24 hours. The tests were leveraged from the reference device HeartSpan® Steerable Introducer Kit (K132164). The results conclude that the Sheath material passed the required ISO 10993 biocompatibility tests and thus support the use of the materials according to their indications for use.

The device were subjected to the following tests:

- C3a Complement Activation Assay
- SC5b-9 Complement Activation Assay
- ASTM Partial Thromboplastin Time
- USP Pyrogen Study – Material Mediated
- ISO Systemic Toxicity Study in Mice
- ISO Intracutaneous Study in Rabbits
- ASTM Hemolysis Study



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Cytotoxicity Study Using the ISO Elution Method
ISO Guinea Pig Maximization Sensitization Test
Thromboresistance Study in the Sheep, Heparinized Model

The device specification requirements for functionality, performance specifications, physical characteristics, safety characteristics, labeling, packaging and shipping, shelf life, and sterilization all passed the specific tests and engineering evaluations. The testing demonstrates that the device does not raise questions of safety or effectiveness when compared to the predicate.

5.6 Conclusion

CardioFocus, Inc. considers its HeartLight Deflectable Sheath to be substantially equivalent to the currently marketed predicate device FlexCath Steerable Sheath (K123591). This assessment is based upon analysis of identical indications for use and similar technological characteristics, design, performance and materials used.

Bench testing was performed to support substantial equivalence between the proposed device, HeartLight® 12F Deflectable Sheath and the predicate FlexCath® Advance™ Steerable Sheath (K123591). The Design Verification testing demonstrated that design outputs met relevant performance and functional requirements and conforms to the intended use/indications of use for the device. The 12F Deflectable Sheath has identical intended use/ indications for use and performance specifications to that of the FlexCath® Advance™ Steerable Sheath cleared under K123591. Therefore the bench testing performed demonstrates substantial equivalence with the testing and intended use of primary predicate. The biocompatibility testing does not raise questions of safety or effectiveness since the material used for the 12F Deflectable sheath is the same as the reference device cleared under K132164 and has been in the market for a similar indications for use.

Design verification and biocompatibility testing results indicate that the properties and performance of the device are suitable for its intended use and no new issues of safety or effectiveness have been raised.