

Cardiosolutions
Dexterity™ Steerable Introducer
Special Premarket Notification 510(k)
December 31, 2013

007-1

R140015
FEB - 5 2014

SECTION 7.0
SPECIAL 510(k) SUMMARY

510(k) Summary

Special 510(k)

As required by section 807.92(c)

Company Name	Cardiosolutions Inc.		
Address	375 West St. West Bridgewater MA 02379 Phone: 781-344-0801 Fax: 781-344-0803		
Contact Person	Christine Santagate		
Date Prepared	December 17, 2013		
Trade Name	Dexterity™ Steerable Introducer		
Common Name	Steerable Introducer		
Classification Name	Catheter Introducer		
Product Code	DYB, DRA		
Regulation #	21 CFR 870.1340		
Class	2		
Panel	Cardiovascular		
Predicate Devices	Percu-Pro™ Steerable Introducer K120086, 131332		
Device Description	The Cardiosolutions Dexterity™ Steerable Introducer is provided as a 9Fr and 14Fr Introducer. The set also consists of the following components based on the model#:		
	Size and Working Length	Included Accessories	
	14FR 65 and 85 CM	Dilator	Stylet Tear-away introducer sheath
	14Fr 105 CM	Dilator	NA Tear-away introducer sheath

	9Fr 65CM	NA	Curved Stylet	NA
	<p>The Dexterity steerable introducer is designed to provide flexible catheter positioning in the cardiac anatomy. The steerable introducer provides both proximal tip and distal tip steering and is fitted with a hemostasis valve to minimize blood loss during catheter introduction and/or exchange. A sideport with stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The introducer sheath is reinforced Pebax and the distal tip has a radiopaque marker to improve fluoroscopic visualization. The device is provided in various diameters and working lengths. The device is provided sterile and is intended for single use only.</p> <p>The purpose of this submission is to add an additional device working length, 105 CM, to the 14Fr Introducer product offering. In addition the intended use statement is modified to include the term percutaneous for clarification only. This change is not a change to the intended use of the device.</p>			
Intended Use	<p>The Dexterity™ Steerable Introducer is intended to be used for the percutaneous introduction of various cardiovascular catheters into the heart, including the left side of the heart through the inter-atrial septum.</p>			
Safety and Performance Testing	<p>No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices.</p> <p>The materials used in the 14 Fr 105 CM Dexterity™ Steerable Introducer are identical to the Dexterity™ Steerable Introducer predicate device. No additional biocompatibility is required.</p> <p>Design verification testing performed on the modified device consisted of mechanical testing conducted in accordance with the ISO 10555 Sterile, single-use intravascular catheters Part 1: General requirements (as amended, 1999, 2004) and in consideration of FDA Guidance on Premarket Notification 510(k) Submission for Short Term and Long Term Intravascular Catheters. The following tests were completed:</p> <ul style="list-style-type: none"> ○ Visual Surface Inspection ○ Dimensional Verification ○ Corrosion Resistance ○ Tensile Break Force ○ Tip Separation Force ○ Freedom from Leakage Under Pressure ○ Air Leakage During Aspiration ○ Luer Hub Compliance ○ Flexural Fatigue Tolerance ○ <i>In Vitro</i> Simulated Use Studies ○ Functional Performance Testing ○ Radiopacity 			

	<ul style="list-style-type: none">○ Shelf Life <p>All test results demonstrate that the properties and performance of the device are substantially equivalent to the predicate device and suitable for its intended use.</p>
Substantial Equivalence	<p>The 14Fr 105 CM Dexterity™ Steerable Introducer is substantially equivalent to the predicate devices in terms of intended use, design, materials, technology, and function. There are no differences between devices which would raise new issues of safety or effectiveness.</p>



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

February 5, 2014

Cardiosolutions Inc.
Christine Santagate
Manager of Regulatory Consulting Services
375 West St.
West Bridgewater, MA 02379

Re: K140015

Trade/Device Name: Cardiosolutions Dexterity Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter, Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: January 7, 2014
Received: January 8, 2014

Dear Ms. Santagate,

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



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 Statement

510(k) Number: K140015

Device Name: Dexterity™ Steerable Introducer

Indications for Use:

The Dexterity™ Steerable Introducer is intended to be used for the percutaneous introduction of various cardiovascular catheters into the heart, including the left side of the heart through the inter-atrial septum.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

A handwritten signature in black ink, appearing to read "M. Hilleman", is written over a stylized logo. The logo consists of the letters "FDA" in a bold, blocky font, with the "F" and "D" being larger and more prominent than the "A".