COOK VASCULAR INCORPORATED
1186 MONTGOMERY LANE
VANDERGRIFT, PA 15690-6065 U.S.A.
PHONE: 724.845.8621 TOLL FREE: 800.245.4715
WWW.COOKMEDICAL.COM

JUL 0 1 2014

5.0 510(k) SUMMARY

Evolution® RL Controlled-Rotation Dilator Sheath Set and Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set
21 CFR §870.1310
Date Prepared: July 1, 2014

Submitted By:

Applicant:	Cook Vascular, Inc.
Contact:	Thomas J. Kardos
Applicant Address:	Cook Vascular, Inc. 1186 Montgomery Lane Vandergrift, PA 15690
Contact Phone Number:	(724) 845-8621 x2225
Contact Fax Number:	(724) 845-2848

Device Information:

Trade Name:	**Evolution® RL Controlled-Rotation Dilator Sheath Set** **Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set**
Common Name:	Vessel Dilator for Percutaneous Catheterization
Classification Name:	Dilator, Vessel, for Percutaneous Catheterization
Regulation:	21 CFR §870.1310
Product Code:	DRE

Predicate Device:

- The predicate device is the Evolution® Mechanical Dilator Sheath Set (Cook Vascular, Inc., K061000).

Device Description:

The Evolution® RL Controlled-Rotation Dilator Sheath Set is constructed of two coaxial sheaths connected to a handle capable of mechanically rotating the inner sheath. In use, the coaxial sheaths are advanced over an indwelling catheter or cardiac lead. The inner sheath (available in 9, 11, and 13 French diameters) is designed to rotate in either a uni-rotational or bi-rotational manner by pulling the trigger in the handle assembly. As the inner sheath is advanced, the rotation of the sheath assists in dilation of any binding tissue which may be anchoring the catheter or lead to the inner vascular or inner cardiac wall. The outer coaxial sheath can be used to stabilize the cardiac wall at the point of lead/catheter tip attachment to allow for detachment and removal (counter traction technique). The device has a working length of 40.6 centimeters.

The Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set is constructed of two coaxial sheaths connected to a handle capable of mechanically rotating the inner sheath. The outer sheath has winged control tabs located at its proximal (handle) end. The sheaths are advanced over an indwelling catheter or cardiac lead. The inner sheath (available in 9 and 11 French diameters) is designed to rotate in in either a uni-rotational or bi-rotational manner by pulling the trigger in the handle assembly. As the inner sheath is advanced, the rotation of the sheath assists in dilation of any binding tissue which may be anchoring the catheter or lead to the inner vascular or inner cardiac wall. The outer coaxial sheath can be used to stabilize the cardiac wall at the point of lead/catheter tip attachment to allow for detachment and removal (counter traction technique). The devices have a working length of 13.6 centimeters.

Intended Use:

The Evolution® RL Controlled-Rotation Dilator Sheath Set and the Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set are intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects. The intended use is the same as for the predicate device, the Evolution® Mechanical Dilator Sheath Set (K061000).

Comparison to Predicates:

The Evolution® RL Controlled-Rotation Dilator Sheath Set and the Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set are substantially equivalent to the predicate device, the Evolution® Mechanical Dilator Sheath Set (K061000), in that these devices have similar designs, methods of construction and operation, and indications for use.

Technological Characteristics:

The following tests have been conducted to ensure reliable design and performance under the specified design requirements. These tests include:

1. Fatigue and Binding Testing – Testing was performed with the requirement that the sheaths should not kink, buckle, or fracture, and both the sheaths and the handle should remain functional after 50 cycles of flexing no less than 90° in opposite directions. The results showed that these predetermined acceptance criteria were met. The predetermined acceptance criteria established for this test corresponded to the acceptance criteria utilized for the predicate device cleared under K061000, with the exception of requiring 10 additional cycles of flexing as compared to the acceptance criteria for the predicate.

2. Handle Cycling Testing – Testing was performed with the requirement that the sheaths should not kink, buckle, or fracture, and both the sheaths and the handle should remain functional after being subjected to rotation via 2000 pulls of the handle trigger while fixed in a curved position to a radius of 3.5 inches. The results showed that these predetermined acceptance criteria were met. The predetermined acceptance criteria established for this test corresponded to the acceptance criteria utilized for the predicate device cleared under K061000.

3. Buckling Testing – Testing was performed with the requirement that the sheaths should not kink, buckle, or fracture should remain functional after being subjected to rotation via 2000 pulls of the handle trigger while fixed in a curved position to a radius of 3.5 inches. The results showed that these predetermined acceptance criterion was met. The predetermined acceptance criteria established for this test corresponded to the acceptance criteria utilized for the predicate device cleared under K061000.

4. Pull Testing/Sheath Pull Assembly Testing – Testing was performed with the requirement that each joint in the devices should withstand a minimum of 20 pounds of pull force, after being subjected to the previous tests. The results showed that these predetermined acceptance criterion

was met. The predetermined acceptance criteria established for this test corresponded to the acceptance criteria utilized for the predicate device cleared under K061000.

5. Testing of Reciprocating Action – Testing was performed with the requirement that the rotational mechanism should remain functional through 1000 cycles of alternating clockwise and counterclockwise rotation. The results showed that these predetermined acceptance criterion was met.

6. Testing of Continuous Clockwise Rotation – Testing was performed with the requirement that the rotational mechanism should remain functional through 1000 cycles of clockwise rotation. The results showed that these predetermined acceptance criteria were met.

7. Testing of Continuous Counterclockwise Rotation – Testing was performed with the requirement that the rotational mechanism should remain functional through 1000 cycles of counterclockwise rotation. Thus, the predetermined acceptance criteria were met.

8. Peel Force Testing – Testing shows that the peel-away outer sheath of the Evolution Shortie RL Controlled-Rotation Dilator Sheath Set should require a peel force of less than 8 pounds. Thus, the predetermined acceptance criteria were met.

9. Biocompatibility Testing – Per ISO 10993-1:2009, the proposed devices were classified as external communicating devices in contact with circulating blood for a limited (≤ 24 hours) duration. The following tests were completed and the biocompatibility was deemed acceptable: Cytotoxicity, Sensitization, and Irritation/Intracutaneous Reactivity, Systemic Toxicity, Hemolysis, Partial Thromboplastin Time, C3a Completement Activation, SC5b-9 Complement Activation, and Pyrogenicity.

10. Sterility Testing – The proposed devices were evaluated for bioburden levels, endotoxin levels, and ethylene oxide and ethylene chlorohydrin residuals. Their sterility was deemed acceptable.

Conclusion:

The results of these tests support a conclusion that the Evolution® RL Controlled-Rotation Dilator Sheath Set and the Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set met the design input requirements based on the intended use and support the conclusion that these

devices do not raise new questions of safety or effectiveness as compared to the predicate and are therefore substantially equivalent to the predicate device, the Evolution® Mechanical Dilator Sheath Set (Cook Vascular, Inc., K061000).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 1, 2014

Cook Vascular, Inc.
Thomas Kardos
Vice President, Regulatory Affairs
1186 Montgomery Lane
Vandergrift, Pennsylvania 15690

Re: K141148
Trade/Device Name: Evolution RL Controlled-Rotation Dilator Sheath Set, Evolution Shortie RL Controlled-Rotation Dilator Sheath Set
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catherization
Regulatory Class: Class II
Product Code: DRE
Dated: May 2, 2014
Received: May 5, 2014

Dear Thomas Kardos,

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,

Linda J. Ricci -S

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

Enclosure

COOK VASCULAR INCORPORATED
1186 MONTGOMERY LANE
VANDERGRIFT, PA 15690-6065 U.S.A.
PHONE: 724.845.8621 TOLL FREE: 800.245.4715
WWW.COOKMEDICAL.COM

4.0 INDICATIONS FOR USE

INDICATIONS FOR USE

510(k) Number (if known): K141148

Device Name: Evolution® RL Controlled-Rotation Dilator Sheath Set and Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set

Indications for Use:

The Evolution® RL Controlled-Rotation Dilator Sheath Set and the Evolution® Shortie RL Controlled-Rotation Dilator Sheath Set are intended for use in patients requiring the percutaneous dilation of tissue surrounding cardiac leads, indwelling catheters and foreign objects.

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)

Linda J. Ricci -S

Concurrence of CDRH, Office of Device Evaluation (ODE)