K072526

OCT 5 ˇ 2007

510(k) Summary

Micrus Endovascular Corporation
Micrus® Courier Enzo™ Microcatheter 0.0190"

This 510(k) summary for the Micrus® Courier Enzo™ Microcatheter 0.0190"is submitted in accordance with the requirements of 21 C.F.R. § 807.92.

GENERAL INFORMATION

Manufacturer:
Micrus Endovascular Corporation
821 Fox Lane
San Jose, California 95131
Phone: (408) 433-1400
Est. Registration No. 2954740

Contact Person:
R. Michael Crompton
Vice President, Regulatory / Clinical Affairs
& Quality

Date Prepared:
September 6, 2007

DEVICE DESCRIPTION

Classification:
Class II

Trade Name:
Micrus® Courier Enzo™ Microcatheter 0.0190"

Generic/Common Name:
Diagnostic intravascular catheter (21 CFR § 870.1200)

PREDICATE DEVICE

Micrus® Courier Enzo™ Microcatheter 0.0170" (reference: K070456)

INTENDED USE

The Micrus Courier microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into peripheral, coronary, and neuro vasculature.

K072526

DEVICE DESCRIPTION

The Micrus® Courier Enzo™ Microcatheter 0.0190" in a diagnostic intravascular catheter with an in-vivo shapeable tip which deflects under operator control at an angle of ±90° from the neutral position. The Micrus® Courier Enzo™ Microcatheter 0.0190"is designed with a feature which allows the clinician to adjust the catheter tip shape *in-vivo* by turning a knob. No shaping tool is required. This design feature allows the clinician to adjust the catheter tip shape to accommodate variations in patient anatomy without having to remove the catheter from the patient's body in order to re-shape it.

The accessories for the Micrus Courier Enzo Microcatheter 0.0190", which are not supplied as part of the sales unit, are identical to those for the Micrus Courier Pre-Shaped Microcatheters and include:

- Guiding catheter (generally, 5-7F)
- Guidewire compatible with the microcatheter
- Rotating Hemostatic Valves (RHV); two (2) required
- 3-way stopcock
- 1-way valve
- Femoral sheath
- Continuous Saline Flush Set-ups with Pressure Bags, one as a flush for the guiding catheter and the other as a flush for the microcatheter

SUBSTANTIAL EQUIVALENCE

The Micrus® Courier Enzo™ Microcatheter 0.0190"is substantially equivalent to the predicate device identified previously. The Micrus® Courier Enzo™ Microcatheter 0.0190"is substantially equivalent to the predicate device with regard to intended use, shape of distal tip angle, materials, design, and function.

Verification testing conducted on the Micrus® Courier Enzo™ Microcatheter 0.0190" demonstrates the device is substantially equivalent to the predicate device and does not raise new questions regarding safety and effectiveness with respect to diagnostic intravascular catheters when used in accordance with its Instructions for Use.

CONCLUSION

As described in this 510(k) Summary, Micrus Endovascular Corporation considers the Micrus® Courier Enzo™ Microcatheter 0.0190" substantially equivalent to the Micrus® Courier Enzo™ Microcatheter 0.0170" based on a comparison of intended uses and the results of *in-vitro* tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Micrus Endovascular Corporation
c/o Mr. R. Michael Crompton
Vice President, Regulatory/Clinical Affairs & Quality
821 Fox Lane
San Jose, CA 95131

OCT 5 ' 2007

Re: K072526
Trade/Device Name: Micrus® Courier Enzo™ Microcatheter 0.0190"
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: September 6, 2007
Received: September 7, 2007

Dear Mr. Crompton:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K072526

Statement of Indications for Use

510(k) Number (if known): K_____

Device Name: Micrus® Courier Enzo™ Microcatheter – 0.0190"

Indications for Use: The Micrus Courier microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into peripheral, coronary, and neuro vasculature.

Prescription Use___X____ AND/OR Over-the-Counter Use_____
(Per 21 C.F.R. 801 Subpart D) (21 C.F.R. 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072526