K083922

## 510(k) Summary

MAY - 6 2009

**Micrus Endovascular Corporation**
**Micrus® Courier® Flex™ Microcatheter**

This 510(k) Summary for the Micrus Courier Flex Microcatheter 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, CA 95131
Phone: 408-433-1400
Est. Registration No. 2954740

**Contact Person:**
Patrick Lee
Manager, Regulatory Affairs
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**Date Prepared:** December 29, 2008

### DEVICE CLASSIFICATION

**Classification:** Class II

**Trade Name:** Micrus Courier Flex Microcatheter

**Product Code:** DQO

**Generic/Common Name:** Catheter, Intravascular, Diagnostic (21CFR § 870.1200)

### PREDICATE DEVICES

- 510(k) no. K060116, Courier Microcatheter, May 12, 2006

### INTENDED USE

Micrus Courier Flex Microcatheters are intended to aid in the delivery of diagnostic agents, such as contrast media, as well as therapeutic agents, such as occlusion coils, into the peripheral, coronary and neurovasculature.

## DEVICE DESCRIPTION

Micrus Courier Flex Microcatheters are variable stiffness, single lumen catheters designed to aid the physician in accessing small, tortuous vasculature when used with a guiding catheter and steerable guide wire. Multiple levels of stiffness ranging from a highly flexible tip to a semi-rigid proximal section along the length of the catheter are designed to aid the physician in tracking over guide wires without displacement of the wire. The microcatheters have an outer hydrophilic coating that reduces friction during manipulation in the vessel. The lubricious PTFE-coated inner lumen is designed to facilitate movement of guide wires and other devices. A shaft marker, located 90 cm from the distal tip, is provided to expedite microcatheter insertion to the depth of standard guide catheters (90 cm long). Two marker bands, one at the catheter tip and another 3 cm proximal to the tip, are radiopaque to facilitate fluoroscopic visualization. A luer fitting located on the end of the catheter hub can be used to attach accessories. All microcatheters are packaged with a steam shaping mandrel accessory.

## SUBSTANTIAL EQUIVALENCE

The Micrus Courier Flex Microcatheter is substantially equivalent to the Micrus Courier Microcatheter in terms of intended use, design, specifications, and materials. The microcatheter is intended to aid in the delivery of diagnostic agents, such as contrast media, as well as therapeutic agents, such as occlusion coils, into the peripheral, coronary and neurovasculature. The Micrus Courier Flex Microcatheter uses the same methods and materials in construction, packaging, and sterilization as its predicates. The modification to the device has not altered the fundamental technology of the predicate devices.

## CONCLUSION

As described in this 510(k) Summary, Micrus Endovascular Corporation considers the Micrus Courier Flex Microcatheter to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 6 2009

Micrus Endovascular Corporation
c/o Mr. Patrick Lee
Manager, Regulatory Affairs
821 Fox Lane
San Jose, CA 95131

Re: K083922
Trade/Device Name: Micrus® Microcatheter, Courier® Flex
Regulation Number: 21 CFR 870.1200
Regulation Name: Catheter Intravascular, Diagnostic
Regulatory Class: II
Product Code: DQO
Dated: April 7, 2009
Received: April 8, 2009

Dear Mr. Lee:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

# Indications for Use

**510(k) Number (if known):** _____

**Device Name:** Micrus Microcatheter "Courier Flex"

**Indications For Use:**

Micrus Courier Flex Microcatheters are intended to aid in the delivery of diagnostic agents, such as contrast media, as well as therapeutic agents, such as occlusion coils, into the peripheral, coronary and neurovasculature.

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)

for Bruckheimer 5/5/09

**(Division Sign-Off)**
**Division of Cardiovascular Devices**

**510(k) Number** K083922