510(k) Summary
Micrus Microcatheters "Courier Pre-Shaped"

The Assigned 510(k) number is: K061963

AUG - 4 2006

Submitter Name and Address:	Micrus Endovascular Corp. 821 Fox Lane San Jose, CA 95131
Contact Name:	Patrick Lee, Regulatory Affairs Specialist Phone: 408-433-1428 Fax: 408-433-1401 Email: plee@micruscorp.com
Preparation Date:	August 1, 2006
Device Name and Classification:	Micrus Microcatheter "Courier Pre-Shaped" 170–45°, 170–90°, 190–45°, & 190–90° Common Name: Courier Pre-Shaped Microcatheter Classification Name: Microcatheter, intravascular, diagnostic Regulatory Class II
Predicate Device:	Micrus Microcatheter, "Courier" Straight, 510(k) number K060116 Boston Scientific, Excelsior 1018 and SL-10 Microcatheters, 510(k) number K042568
Device Description:	The Micrus Microcatheters are tubular devices with a single lumen designed for insertion into the cardiovascular system for diagnostic and therapeutic purposes.
Device 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.

Comparison to Predicate Device:

The Micrus "Courier Pre-Shaped" microcatheters are substantially equivalent to the predicate device Micrus "Courier Straight" microcatheters in terms of design, materials, and function. They are both made of the same materials and coated with the same hydrophilic coating, they have the same shaft design with the same radiopaque markers; they have the same proximal and distal inner diameters and same outer diameters; the have the same effective shaft lengths. The Micrus Courier Pre-Shaped microcatheters have tips that are already shaped to either a 45° or 90° whereas the predicate Courier Straight microcatheters have straight tips. The tips of both types of microcatheters can be further steam-shaped by the physician at the time of use.

The Micrus "Courier Pre-Shaped" microcatheters are also substantially equivalent to the predicate device Boston Scientific Excelsior 1018 and SL-10 microcatheters (both of which have 90° tips) in terms of its ability to track through a tortuous path with minimal force. The Micrus "Courier Pre-Shaped" microcatheters had lower peak and lower average tension / compression than the predicate Excelsior 1080 and SL-10.

Conclusion:

Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by Micrus Endovascular Corporation, it is concluded that the Micrus Microcatheter, "Courier" with Pre-Shaped tip is substantially equivalent to the predicate devices in safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 4 2006

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

Re: K061963
Micrus Microcatheter "Courier Pre-Shaped"
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular, Diagnostic
Regulatory Class: Class II (two)
Product Code: DQO
Dated: July 11, 2006
Received: July 12, 2006

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 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

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): K061963

Device Name: Micrus Microcatheters "Courier Pre-Shaped"

Model #s: MPS170045-00, MPS170090-00, MPS190045-00, MPS190090-00

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 ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061763