

AUG 27 2008

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5.0 510(k) Summary

Micrus Endovascular Corporation Micrus® Ascent™ Occlusion Balloon Catheter

This 510(k) Summary for the Micrus® Ascent™ Occlusion Balloon Catheter 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
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Date Prepared: March 25, 2008

DEVICE CLASSIFICATION

Classification: Class II

Trade Name: Micrus® Ascent™ Occlusion Balloon Catheter

Generic/Common Name: catheter, intravascular occluding, temporary (21CFR § 870.4450)

PREDICATE DEVICES

- 510(k) no. K984214, Cordis Temporary Occlusion Balloon Catheter, Aug 10, 1999
- 510(k) no. K993292, Sentry Occlusion Balloon Catheter, May 23, 2000
- 510(k) no. K011656, MTI Hyperform Occlusion Balloon Catheter, Jun 20, 2001
- 510(k) no. K060116, Courier Straight Microcatheter, May 12, 2006

INTENDED USE

The Micrus Ascent Occlusion Balloon Catheter is intended for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired and offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The Micrus Ascent Occlusion Balloon Catheter is also intended to assist in the delivery of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils, into the peripheral and neuro vasculature.

DEVICE DESCRIPTION

The Micrus® Ascent™ Occlusion Balloon Catheter is a coaxial dual lumen balloon catheter comprised of an inner guidewire lumen and a separate outer lumen to inflate and deflate the balloon. The balloon catheter is designed for use over any .014” or smaller guidewire. The balloon can be inflated and deflated independently of guidewire position. The balloon is equipped with a vent hole for easy preparation and removal of air from the balloon, and with two radiopaque markers for balloon positioning.

SUBSTANTIAL EQUIVALENCE

The Micrus Ascent Occlusion Balloon Catheter is substantially equivalent to the MTI Hyperform Occlusion Balloon Catheter, the Cordis Commodore Occlusion Balloon Catheter, and the Target Sentry Occlusion Balloon Catheter in terms of intended use, design, specifications, and materials. These systems are all intended for use to assist in the temporary occlusion of peripheral vessels. The Micrus Ascent Occlusion Balloon Catheter is substantially equivalent to the Micrus Courier Microcatheter in terms of intended use, specifications, and materials. The Micrus Ascent Occlusion Balloon Catheter 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 Ascent Occlusion Balloon Catheter to be substantially equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 27 2008

Micrus Endovascular Corporation
% Mr. Patrick Lee
Regulatory Affairs Specialist
821 Fox Lane
San Jose, California 95131

Re: K080861

Trade/Device Name: The Micrus Ascent Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp.
Regulatory Class: II
Product Code: MJN
Dated: August 25, 2008
Received: August 26, 2008

Dear Mr. Patrick 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.

Page 2 – Mr. Patrick Lee

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) 276-0115. 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 Biometric's (OSB's) 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,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 Indications for Use

510(k) Number (if known): _____

Device Name: The Micrus Ascent Occlusion Balloon Catheter

Indications For Use:

The Micrus Ascent Occlusion Balloon Catheter is intended for use in the blood vessels of the peripheral and neuro vasculature where temporary occlusion is desired and offers a vessel selective technique of temporary vascular occlusion which is useful in selectively stopping or controlling blood flow. The Micrus Ascent Occlusion Balloon Catheter is also intended to assist in the delivery of diagnostic agents such as contrast media, and therapeutic agents such as occlusion coils, into the peripheral and neuro vasculature.

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)



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K080861

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