Penumbra

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K072718

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c)

510(k) Number	
Date Summary Prepared	September 20, 2007
Trade Name	Penumbra System™
Common Name	Percutaneous Catheter
Classification Name	Percutaneous Catheter (21 CFR Part 870.1250; Product Code NRY)
Submitted By	Penumbra, Inc. 2401 Merced Street, Suite 200 San Leandro, CA 94577
Contact	Theresa Brander-Allen VP of Regulatory and Quality Tel: 510-618-3223 Fax: 510-352-1766 tballen@penumbrainc.com

DEC 2 8 2007

Predicate Devices
Merci Retriever models X5 and X6 (K033736) and Merci Micro Catheter (K003086) Manufactured by Concentric Medical, Inc.

Device Description
The Penumbra System consists of four devices that work as a system to remove thrombus including the Penumbra Reperfusion Catheter, Penumbra Separator, and Aspiration Tubing. The Penumbra System is used with the Penumbra Aspiration Pump (K051758).

Materials used in the Penumbra System devices are manufactured from medical grade materials that are commonly used in the industry, are similar or identical to the predicate devices, and have historically been demonstrated to be both biocompatible and suitable for this use.

Intended Use
The Penumbra System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8

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hours of symptom onset. The indication statement of the Penumbra System is substantially equivalent to the legally marketed predicate devices.

Substantial Equivalence

The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to the existing, legally marketed, predicate devices. Therefore, Penumbra believes the Penumbra System is substantially equivalent to the predicate devices.

Testing

Bench testing, *in vitro* testing, *in vivo* testing, and a clinical study have been performed on the device materials, components, subassemblies, and final assemblies. The devices tested met the specifications and the outcome measures of the clinical protocol.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2007

Penumbra, Inc.
% Ms. Theresa Brander-Allen
V. P., Regulatory and Quality
2401 Merced Street, Suite 200
San Leandro, CA 94577

Re: K072718
Trade/Device Name: Penumbra System™
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: NRY
Dated: November 30, 2007
Received: December 3, 2007

Dear Ms. Brander-Allen:

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) 276-0115. 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

Penumbra

Indications for Use

510(k) Number (if known):

Device Name: Penumbra System™

Indications for Use: The Penumbra System™ is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.

Prescription Use X AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 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 K072718