SEP 21 2009

Penumbra

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	K090752
Date Summary Prepared	March 19, 2009
Trade Name	Penumbra Reperfusion Catheter 054 and Penumbra Separator 054
Common Name	Percutaneous Catheter
Classification Name	Percutaneous Catheter (21 CFR Part 870.1250; Product Code NRY)
Submitted By	Penumbra, Inc. 1351 Harbor Bay Parkway Alameda, CA 94502
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Predicate Devices
Penumbra System™ and Neuron™ Intracranial Access System, manufactured by Penumbra, Inc.

Device Description
The Penumbra System™ consists of three 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.

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.

Penumbra

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 hours of symptom onset.

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 that the Penumbra Reperfusion Catheter 054 and Penumbra Separator 054 are substantially equivalent to the predicate devices.

Testing

Bench testing, *in vitro* testing, and *in vivo* testing have been performed on the device materials, components, subassemblies, and final assemblies. The devices tested acceptably met the specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 21 2009

Penumbra, Inc.
c/o Seth Schulman
Director, Regulatory Affairs
1351 Harbor Bay Parkway
Alameda, CA 94502

Re: K090752
Trade/Device Name: Penumbra Reperfusion Catheter 054, Penumbra Separator 054
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II
Product Code: NRY
Dated: September 1, 2009
Received: September 2, 2009

Dear Mr. Schulman:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090752

Indications for Use

510(k) Number (if known): K090752

Device Name:	Penumbra Reperfusion Catheter 054, Penumbra Separator 054
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 (within 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)

Kristen Bowsher
(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K090752