K070970 p 1 of 2

Penumbra

AUG 17 2007

## 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)

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|---|---|
| 510(k) Number | |
| Date Summary Prepared | April 4, 2007 |
| Trade Name | Neuron™ Intracranial Access System |
| Common Name | Percutaneous Catheter |
| Classification Name | Percutaneous Catheter<br>(21 CFR Part 870.1250; Product Code DQY) |
| Submitted By | Penumbra, Inc.<br>2401 Merced Street, Suite 200<br>San Leandro, CA 94577 |
| Contact | Theresa Brander-Allen<br>VP of Regulatory and Quality<br>Tel: 510-618-3223<br>Fax: 510-352-1766<br>tballen@penumbrainc.com |

Predicate Devices
- Penumbra Balloon Guide Catheter (K053491), manufactured by Penumbra, Inc.
- Guider Softip Guiding Catheter XF 5F (K010853), manufactured by Boston Scientific Corporation

Device Description
The Neuron Intracranial Access System has a Neuron Delivery Catheter (outer catheter), which is available with a diameter of 6F proximal and 5F distal, and a Neuron Select Catheter (inner catheter), which measures 3.5F and has multiple tip configurations. The Neuron Delivery Cather may be used with a guidewire or with the Neuron Select Catheters.

Materials used in the Neuron Intracranial Access 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.

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Intended Use

The Neuron Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. The indication statement of the Neuron Intracranial Access 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 Neuron Intracranial Access System is 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

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2007

Penumbra, Inc.
c\o Ms. Theresa Brandner-Allen
VP of Regulatory and Quality
2401 Merced St, Suite 200
San Leandro, CA 94577

Re: K070970
Trade/Device Name: Neuron™ Intracranial Access System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II
Product Code: DQY
Dated: August 10, 2007
Received: August 13, 2007

Dear Ms. Brandner-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) 276-0120. 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 Biometrics' (OSB) 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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indications for Use

510(k) Number (if known): K070970

Device Name: Neuron™ Intracranial Access System

Indications for Use: The Neuron™ Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

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 Cardiovascular Devices

510(k) Number K070970

Page __ of ___