K100769

10. 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

MAY 21 2010

(as required by 21 CFR § 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra, Inc. is providing the summary of Substantial Equivalence for the Penumbra System Separator Flex.

10.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502, USA

10.2 Sponsor Contact Information

Michaela Mahl
Principal Regulatory Specialist
Phone: (510) 748-3288
FAX: (510) 217-6414
Email: michaela.mahl@penumbrainc.com

10.3 Date of Preparation of 510(k) Summary

April 20, 2010

10.4 Device Trade or Proprietary Name

Penumbra System® Separator™ Flex

10.5 Device Classification

Regulatory Class:	II
Classification Panel:	Cardiovascular
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR § 870.1250
Product Code:	NRY

10.6 Predicate Devices

510(k) Number / Clearance Date	Name of Predicate Device	Name of Manufacturer
K090752 / 21 Sep 2009	Penumbra Reperfusion Catheter 054, Penumbra Separator 054	Penumbra, Inc.
K072718 / 28 Dec 2007	Penumbra System [026, 032, 041]	Penumbra, Inc.

10.7 Comparison to Predicate Devices

	Penumbra System Separator [026, 032, 041, 054]	Penumbra System Separator Flex [026, 032, 041, 054]
510(k) No.	K072718 & K090752	To be determined
Classification	Class II, NRY	SAME
Indication	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.	SAME
Materials		
Core wire	Stainless Steel	Nitinol Wire
Coating	PTFE GREEN PC	PTFE GREEN PC Low Cure PTFE
Proximal wire		
Outer coil	Stainless Steel	SAME
Core wire	Stainless Steel Core Wire	Nitinol Core Wire
Solder joint	Silver Solder (95% Sn / 5%Ag)	SAME
Distal tip		
Outer coil	Stainless Steel	SAME
Inner coil	Platinum Alloy	SAME
Solder joint	Gold Solder (80% Au / 20% Sn) Silver Solder (95% Sn / 5%Ag)	SAME
Separator cone tip	Pebax 40D green (026) ,yellow (032), blue (041), purple (054)	SAME
ID band	Polyolefin (PET)	SAME
Sterilization	EtO	SAME
Shelf-Life	36 Months	SAME

10.8 Device Description

The Penumbra System Separator Flex (026, 032, 041, and 054) is an alternative configuration to the currently available Penumbra System Separators. The Separator Flex utilizes a Nitinol core wire in place of the current stainless steel corewire. The Separator Flex is available in all four current sizes (026, 032, 041, and 054). Both the existing Separators and the subject Separator Flex models will be available to address Physician preference of stainless steel and nitinol. The device is provided sterile, non-pyrogenic, and intended for single use only.

10.9 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.

10.10 Summary of Non-clinical Data

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, a summary of any information regarding safety and effectiveness of the device follows.

Included in this section are descriptions of the testing's, which substantiates the safe and effective performance of the Penumbra System Separator Flex as well as its substantial equivalence to the predicate devices:

- Biocompatibility
- Design Verification (Bench-Top Testing)

The subject Penumbra System Separator Flex met all established requirements.

10.10.1 Biocompatibility

Biocompatibility tests conducted for the Penumbra System Separator Flex were selected in accordance with ISO-10993 -1 (Biological Evaluation of Medical Devices) guidelines for a limited exposure (≤ 24 hours), externally communicating device with circulating blood contact. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices.

ISO-10993 GLP Testing Summary for Separator Flex

Test	Method	Results
In Vitro Cytotoxicity	ISO Elution Test (MEM Extract)	No evidence of cell lysis or toxicity
Acute Intracutaneous Reactivity (Irritation)	ISO Intracutaneous (Intradermal) Injection Test	No evidence of irritation
Acute Systemic Toxicity	ISO Acute Systemic Injection Test	No evidence of systemic toxicity
Rabbit Pyrogen Study	USP Material-Mediated Rabbit Pyrogen Test	No evidence of material-mediated pyrogenicity

Test	Method	Results
Sensitization	ISO Maximization Test for Delayed Hypersensitivity	Non-Sensitizing
Hemo-compatibility		
-In Vitro Hemolysis	ASTM Methode (Extraction & Direct Contact)	Non-hemolytic
-In Vitro Coagulation (PT, PTT)	Prothrombin Time (PT) Assay	Coagulation times are within the normal rang
	Partial Thromboplastin Time (PTT) Assay	Non-Thrombogenic
-Complement Activation	C3a and SC5b-9 through Enzyme Assay	No greater biological response than corresponding control

In summary, non-clinical testing found the Penumbra System Separator Flex to be non-cytotoxic, non-mutagenic, non-reactive (short and long-term implantation), non-sensitizing, a negligible irritant, non-pyrogenic, and non-toxic (acute systemic).

10.10.2 Design Verification (Bench-Top Testing)

Design Verification testing was conducted to evaluate the physical and mechanical properties of the Penumbra System Separator Flex. All studies were conducted using good scientific practices and statistical sampling methods as required by the Penumbra Design Control procedures. All testing was performed using units which were 2x sterilized and met finished goods release requirements. The packaging used for the Penumbra System Separator Flex is identical to the predicate Penumbra System Separator packaging. Therefore, no packaging testing was conducted. The tests performed on the Penumbra System Separator Flex included:

- Dimensional / Visual Inspection (all sizes)
- Simulated Use (all sizes): Reperfusion Catheter / Separator Flex / Aspiration Tubing Assembly Performance
- Separator Flexibility Test (all sizes)
- Separator Flex Bond Joint Test

All performed tests passed successfully.

The physical, mechanical and performance testing of the subject Penumbra System Separator Flex demonstrate that the product is safe and effective for its labeled indications and is Substantially Equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2010

Penumbra, Inc.
c/o Ms. Michaela Mahl, MSBE
Principal Regulatory Specialist
1351 Harbor Bay Pkwy.
Alameda, CA 94502

Re: K100769
Trade/Device Name: Penumbra System® Separator™ Flex (026, 032, 041, 054)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: April 20, 2010
Received: April 21, 2010

Dear Ms. Mahl:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

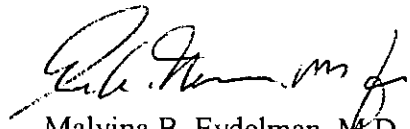
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

Indications for Use

510(k) Number (if known): K100769

Device Name: Penumbra System® Separator™ Flex

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 (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 OF 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 K100769