1 510(K) SUMMARY

JUL 13 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 Cather 025.

1.1 Sponsor/Applicant Name and Address

Penumbra Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502

1.2 Sponsor Contact Information

Seth A. Schulman
Director, Regulatory Affairs
Phone: 510-748-3223
FAX: 510-217-6414
email: seth.schulman@penumbrainc.com

1.3 Date of Preparation of 510(k) Summary

March 22, 2010

1.4 Device Trade or Proprietary Name

TBD

1.5 Device Common/Usual or Classification Name

Catheter, Percutaneous (Product Code: DQY)

1.6 Identification of the Legally Marketed Devices to which Equivalence is Being Claimed:

Name of Predicate Device	Name of Manufacturer (Town, State)	510(k) Number
Penumbra Neuron Intracranial Access System	Penumbra, Inc Alameda, CA	K070970, K082290 & K083125
Excelsior SL-10 / 1018	Boston Scientific Neurovascular Fremont, CA	K042568

1.7 Device Description:

The Penumbra Catheter 025 is a variable stiffness, coil reinforced catheter with a maximum distal outer diameter of 0.040" and a maximum proximal outer diameter of 0.045". It is available with an inner diameter of 0.025".. The Penumbra Catheter 025 has a PTFE-lined lumen, is coil re-enforced, flexible, and hydrophilically coated. The Penumbra Catheter 025 is inserted through a guide catheter or vascular sheath, provides access to the target site and once in place, provides a reinforcing conduit for other intravascular devices. The device is provided sterile and includes a rotating hemostasis valve, tip shaping mandrel and introducer sheath.

The Penumbra Catheter 025 will be available in various tip configurations including straight, 45°, 90° and J, to allow physician ease of device tracking to the target site. The Penumbra Catheter 025 is sterile, non-pyrogenic and intended for single use only.

1.8 Intended Use:

The Penumbra Catheter 025 is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils to the peripheral and neuro vasculature.

1.9 Comparison to Predicate Devices

	Excelsior SL-10 / 1018	Penumbra Neuron Intracranial Access System	Penumbra Catheter 025
510(k) No.	K042568	K070970, K082290 & K083125	To be determined
Classification	Class II, DQY	Class II, DQY	Class II, DQY
Indication	Boston Scientific's Excelsior™ SL-10 Pre-Shaped microcatheter and Excelsior™ 1018™ Pre-Shaped microcatheter are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils to the peripheral, coronary, and neuro vasculature.	The Neuron™ Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	Same as Excelsior SL-10 / 1018
Materials			
- Catheter Shaft/Hub	Thermoplastic, hydrophilic coating	Nylon, PTFE, Polyurethane, hydrophilic coating	SAME
- Catheter shaft support	Metal	Stainless Steel	Nitinol
- Catheter Markerband	Platinum / Iridium	Platinum / Iridium	SAME
- Packaging	PET/PE/Tyvek pouch, polyethylene hoop, SBS carton	PET/PE/Tyvek pouch, polyethylene hoop, SBS carton	SAME (A PET Tray is used instead of the PE Hoop)
Sterilization	EtO	EtO	SAME
Shelf-Life	36-Months	36-Months	SAME

1.10 Summary of Non-clinical Data

1.10.1 Biocompatibility

Biocompatibility tests conducted with the Penumbra Catheter 025 were selected in accordance with ISO-10993 -1 guidelines (Biological Evaluation of Medical Devices) for limited duration (<24 hours), external communicating devices, contacting circulating blood. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices.

ISO-10993 GLP Testing Summary for Penumbra Catheter 025

Test	Method	Result
Cytotoxicity	L929 MEM Elution Test	Slight cell lysis or reactivity
Sensitization	Kligman Maximization	Non-Sensitizing
Intracutaneous Reactivity (Irritation)	Intracutaneous Injection Test	Non-Irritant
Systemic Toxicity (Acute)	ISO Acute Systemic Injection Test	Non-Toxic
Haemocompatibility	Complement Activation	No greater biological response than corresponding control
	Hemolysis	Non-Hemolytic
	In vivo thrombogenicity	Non-Thrombogenic
Pyrogenicity	USP Material Mediated Rabbit Pyrogen Test	Non-Pyrogenic

In summary, non-clinical testing found the Penumbra Catheter 025 to be non-cytotoxic, non-mutagenic, non-reactive (short and long-term implantation), nonsensitizing, a negligible irritant, non-pyrogenic, and non-toxic (acute systemic).

1.10.2 Design Verification (Bench-Top Testing)

The physical, mechanical and performance testing of the Penumbra Catheter 025 demonstrates that the product is substantially equivalent to the currently marketed predicate devices.

Design Verification testing was conducted to evaluate the physical and mechanical properties of the Penumbra Catheter 025. 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 tests performed on the Penumbra Catheter 025 included:

- Dimensional / Visual Inspection

- Trackability
- Friction
- Torsion
- Joint Tensile Strength
- Catheter Burst
- Catheter Flow Rate
- Catheter Elongation
- Kink Resistance
- Corrosion
- GLP Simulated Use

All tests performed passed successfully.

The physical, mechanical and performance testing of the subject Penumbra Catheter 025 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 13 2010

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

Re: K100826
Trade/Device Name: Penumbra Catheter 025
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: March 22, 2010
Received: March 24, 2010

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. 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,

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

Enclosure

2 **STATEMENT OF INDICATION FOR USE**

Indications for Use

510(k) Number (if known): ~~Not Yet Assigned~~ K100826

Device Name: Penumbra Catheter 025 (Trade Name TBD)

Indications for Use:

The Penumbra Catheter 025 is intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils to the peripheral and neuro vasculature.

Prescription Use _X_ **AND/OR** **Over The Counter Use** _____
(Part 21 CFR 801 Subpart D) **(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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100826