K132931

JAN 17 2014

1 510(k) SUMMARY

(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 Apollo™ System.

1.1 Sponsor/Applicant Name and Address

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

1.2 Sponsor Contact Information

Seth A. Schulman
Director, Regulatory Affairs
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1.3 Date of Preparation of 510(k) Summary

December 13, 2013

1.4 Device Trade or Proprietary Name

Apollo™ System

1.5 Device Common/Usual or Classification Name

Endoscope, neurological (Product Code: GWG, 21 CFR §882.1480)

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
Aesculap Aspiration Cannula	Aesculap, Inc. Center Valley, PA	K983365
Penumbra Pump MAX™	Penumbra, Inc. Alameda, CA	K122756

1.7 Device Description:

The Apollo System is a two component surgical instrument designed to aid a physician in the removal of tissue and/or fluids during endoscopic-assisted microneurosurgery. The reusable component has three functions. These functions are vacuum generation, generation of vibrational energy, and saline irrigation. The disposable component, "the Wand" is a rigid cannula to remove tissue and/or fluid with the assistance of vibrational energy and aspiration. The disposable wand is designed to pass through the working channel of various neuro-endoscope trocars allowing visualization of the procedure. The method of action of removal is first vacuum aspiration, which draws the tissue and/or fluid into the lumen of the wand. Next, a vibrational wire is agitated inside the lumen of the wand facilitating movement of any tissue and/or fluid that may otherwise clog the lumen. Saline irrigation has the purpose of providing additional fluid to transport the tissue through the cannula. The irrigation and inner vibration wire components of the disposable wand provide an improvement over existing methods of suction aspiration through a cannula in that the use of the Apollo wand can prevent clogging. Intended users for this device are physicians who have received appropriate training in endoscopic-assisted microneurosurgery.

1.8 Indications for Use:

The Apollo™ System is used for the controlled aspiration of tissue and/or fluids during surgery of the Ventricular System. The Apollo™ disposable wand is inserted through the working channel of a neuroendoscopic trocar.

1.9 Predicate Comparison

	Aesculap Aspiration Cannula	Penumbra Apollo™ System
510(k) No.	K983365	K132931
Classification	Class II, GWG	Class II, GWG
Materials		
Wand	Polymer, Metal	Same
Tubing	N/A (Not supplied with Wand)	Polymer
Canister	N/A	Polymer
Capital Equipment	N/A	General electro-medical equipment compliant with IEC 60601-1 requirements
Sterilization	EtO	Same
Shelf-Life	36-Months	Same

	Aesculap Aspiration Cannula	Penumbra Apollo™ System
Vacuum Source	Hospital based suction system	System based aspiration pump
Vibration Energy Source	N/A	System based vibration generator

	Penumbra Pump MAX™	Penumbra Apollo™ System Pump
510(k) No.	K051758	K132931
Classification	Class II, JCX	Class II, GWG
Indication	The Penumbra Aspiration Pump is intended for general suction use in hospitals or clinics.	The Apollo™ System is used for the controlled aspiration of tissue and/or fluids during surgery of the Ventricular System. The Apollo™ disposable wand is inserted through the working channel of a neuroendoscopic trocar.
Specifications		
IEC 60601-1 Compliance	Yes	**SAME**
IEC 60601-1-2 Compliance	Yes	**SAME**
Voltage	100-115Vac / 230 Vac	**SAME**
Frequency	50 Hz / 60 Hz	**SAME**
Vacuum Range	0-29 inHg (0-98.2 kPa)	**SAME**
Flow Rate	0-23 LPM 0 – 0.8 SCFM	**SAME**
Fuses	Two 5 amp slow blow fuse (250 Vac)	**SAME**
Motor and Pump Description	Oil-less, rotating pump	**SAME**
Sterilization	**Non-Sterile**	**SAME**
Shelf-Life	**N/A**	**SAME**

1.10 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 Apollo™ System as well as its substantial equivalence to the predicate devices:

- Biocompatibility
- Design Verification (Bench-Top Testing)

The subject Apollo™ System components met all established requirements.

1.10.1 Biocompatibility Testing

Biocompatibility tests conducted with Penumbra Apollo™ System were selected in accordance with ISO-10993 -1 guidelines (Biological Evaluation of Medical Devices) for a blood contacting permanent implant device. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices.

Test	Results	Conclusions
In vitro Cytotoxicity (MEM Elution)	Sample extracts exhibited Grade 2 (mild reactivity)	Non-cytotoxic
Sensitization (Magnusson – Kligman Method)	Samples exhibited Grade: 0 (No sensitization response)	Does not elicit sensitization response
Irritation (Intracutaneous Reactivity)	Sample exhibited Grade 0.0 (saline extract) and Grade 0.1 (sesame oil extract)	Non-irritant
Systemic Toxicity		
Systemic Injection (ISO)	No evidence of systemic toxicity from sample extracts	Does not cause systemic toxicity
Material Mediated Pyrogen	No animals had a temperature rise $\geq$ 0.5°C	Non-pyrogenic
Subchronic Toxicity (Subacute Toxicity)	Negative for signs of systemic toxicity	Does not cause systemic toxicity
Hemocompatibility		
Thrombosis (Dog Thrombogenicity)	Device exhibited acceptable reaction to blood	Non-thrombogenic
Coagulation (PTT)	Test article clotting times similar to the predicate device	Acceptable coagulation response
Hematology (Hemolysis – Direct Contact)	Hemolytic index = 1.04% Corrected hemolytic index = 0.23%	Non-hemolytic
Hematology (Hemolysis – Indirect (Extract) Contact)	Hemolytic index = 0.53% Corrected hemolytic index = 0.00%	Non-hemolytic
Genotoxicity		
Ames Mutagenicity	Tests show no zone of increased reversion or of toxicity	Non-mutagenic
Mouse Lymphoma	Non-genotoxic and non-clastogenic)	Non-mutagenic

Test	Results	Conclusions
In vivo Mouse micronucleus	No manifestation of toxicity nor biologically significant erythrpoietic disturbances resulting in delayed mutagenesis. No biologically significant increases in mPCE production.	Non-mutagenic

In summary, non-clinical testing found the Penumbra Apollo™ System to be biocompatible according to the requirements of ISO 10993. Additionally, the product was found to be non-pyrogenic. The physical, mechanical and performance testing of the Penumbra Apollo™ System demonstrate that the product is substantially equivalent to the currently marketed predicate devices.

1.10.2 Bench-top Testing

The physical, mechanical and performance testing of the Apollo™ System components demonstrates that the devices are substantially equivalent to the currently marketed predicate devices:

Design Verification testing was conducted to evaluate the physical and mechanical properties of the Apollo™ System components. 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 Apollo™ System components included:

Test	Methods	Conclusions
Disposable Component Testing		
Tensile Test	The following device connections and bonds were tested for tensile strength: - Sonic Connector to Wire - RHV to Irrigation Catheter Shaft - Proximal Aspiration Tubing to Y-Connector - Wand-Canister Tubing to Male Swivel Connector - Wand-Canister Tubing to Suction Connector - Aspiration Tubing to T-Connector	Component bonds and connections meet or exceed minimal tensile specifications
Corrosion	Device was subjected to testing to evaluate potential for corrosion	Device meets criteria as non-corrosive
Simulated Use	Device tested for simulated use outputs	Device meets or exceeds simulated use testing specifications
Fatigue	Device tested for fatigue based outputs	Device meets or exceeds fatigue testing specifications
Reusable Capital Equipment		
IEC 60601-1	Tested Apollo System for compliance with standard	Complies with standard
IEC 60601-1-2	Tested Apollo System for compliance with standard	Complies with standard
The Apollo System controls shall be easily identifiable by the User.	Tested Apollo System for usability	Controls are easily identifiable
The Apollo System controls shall be validated for Usability	Tested Apollo System for usability	Validated for Usability
The Apollo System reusable component should supply uniform irrigation and vibrational energy for an entire case	Tested Apollo System for functionality	Meets or exceeds specifications to supply uniform irrigation and vibrational energy for an entire case
The Apollo System will be a durable piece of capital equipment	Tested Apollo System for durability	The Apollo System is a

Test	Methods	Conclusions
The Apollo System should be quiet	Tested Apollo System for audible noise level	The Apollo System meets the audible noise specification
The Canister should have volume reference markings	Verified that Canister has volume reference markings	The Canister adequately exhibits the design feature
Canister should be able to withstand maximum pressure delivered by the Apollo System	Tested the Canister at maximum pressure	Canister meets specifications at maximum pressure
Canister lid should include a feature to prevent excess fluid from entering the Apollo System.	Verified that the Canister contains a feature to prevent excess fluids from entering the Apollo System	The Canister adequately exhibits the design feature

All testing met specification. The results of the tests appropriately address the physical and mechanical performance expectations of the device. Based on these overall results, the physical and mechanical properties of the Apollo™ System components are acceptable for the intended use and substantially equivalent to the predicate devices.

1.10.3 Sterilization

The Penumbra Apollo™ System contains several components. The following table identifies which components are sterile or non-sterile. None of the Penumbra Apollo™ System components can be end-user sterilized.

Table 1: Component Sterility

Component	Sterility
Wand	Sterile
Tubing	Sterile
Canister	Non-Sterile
Generator	Non-Sterile
Pump	Non-Sterile
I.V. Pole	Non-Sterile
Footswitch	Non-Sterile

The Penumbra Apollo™ System disposable wands and tubing are packaged and submitted to a contract ISO certified facility for the sterilization of medical devices.

The EtO validation and routine sterilization process of the Penumbra Apollo™ System disposable wands and tubing is based on EN ISO 11135[1] ensuring a Sterility Assurance Level (SAL) of 10^{-6}.

1.10.4 Shelf-Life

The expiration period for the Penumbra Apollo™ System disposable wands and tubing are currently established for 12-months based on 1 yr. accelerated aging test results. The shelf life protocol specifies a test regimen using both accelerated and confirmatory real-time testing methodologies to enable Penumbra to extend the shelf life as additional data becomes available. Upon successful completion of the protocol, Penumbra will maintain a 36-month shelf life for the product.

Penumbra Apollo™ System disposable wands and tubing used in the shelf life studies were produced according to approved production procedures. Acceptance criteria were based on the sterile finished goods testing requirements. All devices used in the shelf-life studies completed 2x sterilization processes prior to test initiation. Packaging materials (both primary and secondary) were tested to validate their properties over the intended shelf life.

1.10.5 Summary of Substantial Equivalence

The Apollo™ System components are substantially equivalent to the predicate devices with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.

[1] EN ISO 11135: 2007 Sterilization of health care products -- Ethylene oxide -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

January 17, 2014

Penumbra, Inc.
% Mr. Seth A. Schulman
Director, Regulatory Affairs
1351 Harbor Bay Parkway
Alameda, CA 94502

Re: K132931
Trade/Device Name: Penumbra Apollo™ System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: December 13, 2013
Received: December 18, 2013

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 contact 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. 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,

Joyce M. Whang -S

for Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological and Physical
Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132931

Device Name: Penumbra Apollo™ System

Indications For Use:

The Apollo™ System is used for the controlled aspiration of tissue and/or fluids during surgery of the Ventricular System. The Apollo™ disposable wand is inserted through the working channel of a neuroendoscopic trocar.

Prescription Use ✓ (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 IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S