



Food and Drug Administration
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March 24, 2016

Penumbra, Inc.
Ms. Mary Rose
Senior Manager, Regulatory Affairs
One Penumbra Place
Alameda, California 94502

Re: K152699
Trade/Device Name: Apollo™ System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
Dated: February 12, 2016
Received: February 16, 2016

Dear Ms. Rose:

This letter corrects our substantially equivalent letter of March 17, 2016.

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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,

Carlos L. Pena -S



Carlos L. Peña, PhD, MS
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)

K152699

Device Name

Apollo™ System

Indications for Use (Describe)

The Apollo System is used for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

(as required by 21 CFR 807.92)

1.1 Submitter

Penumbra Inc.
One Penumbra Place
Alameda, CA 94502, USA

Contact Person: Mary Rose, Senior Manager, Regulatory Affairs
Phone: 510-748-3346
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1.2 Device Trade or Proprietary Name

Apollo™ System

1.3 Device Common/Usual or Classification Name

Endoscope, neurological (Product Code: GWG)

1.4 Primary Device Classification

Regulatory Class:	II
Classification Panel:	Neurology
Classification Name:	Endoscope, neurological
Regulation Number:	21 CFR 882.1480
Product Code:	GWG

1.5 Predicate Devices

Apollo™ System, K132931
SONOTOME™ System, K990572

1.6 Predicate Comparison

Table 1: Predicate Device Comparison			
	SONOTOME™ System	<u>Apollo™ System</u>	<u>Subject Device:</u> Apollo™ System
510(k) No.	K990572	K132931	K152699
Classification	Class II, LFL	Class II, GWG	Class II, GWG
Indications for Use	Breakup and removal of soft tissues in Neurosurgery, GI and affiliated organ surgery, Urology, General surgery, Plastic and reconstructive surgery, Orthopedic, GYN, Thoracic.	The Apollo System is used for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System. The Apollo Wand is inserted through the working channel of a neuro-endoscopic trocar.	The Apollo System is used for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum.
Basic Operating Principle	Metal tip driven by ultrasound causing tissue fragmentation and aspiration through tip.	AC power is converted from the generator into vibrational energy and saline irrigation to the distal tip of the Wand, which removes tissue and/or fluids through an aspiration lumen.	Same as K132931 cleared device.
System Console	Self-contained with ultrasonic, irrigation, and aspiration subsystems.	Self-contained with irrigation and aspiration subsystems. Powered by a generator and vacuum.	Same as K132931 cleared device.
Amplitude of Vibration of tip	240 microns, peak to peak	25 microns, peak to peak	Same as K132931 cleared device.
Vibration Frequency	20 kHz	21 kHz	Same as K132931 cleared device.
Irrigation Flow Rate	10-400 ml/min	30 ml/min	Same as K132931 cleared device.
Aspiration	5-15 in. Hg	0-29 in. Hg	Same as K132931 cleared device.
Disposable	<ul style="list-style-type: none"> Surgical Tips, 	<ul style="list-style-type: none"> Wand 	

Table 1: Predicate Device Comparison			
	SONOTOME™ System	<u>Apollo™ System</u>	<u>Subject Device:</u> Apollo™ System
components	<ul style="list-style-type: none"> • Suction trap, • Irrigation/suction tubing set 	<ul style="list-style-type: none"> • Collection Canister, filter and pump-canister tubing • Irrigation Tubing 	
Power requirements	105-130 v a-c, 60Hz, 500 watts	100-115V (60Hz), 100V (50Hz)	Same as K132931 cleared device.

1.7 Device Description:

The Apollo System is designed to aid a physician in the removal of tissue and/or fluids during image-guided neurosurgery. The reusable components have three functions; 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 be image-guided, such as passing through the working channel of various neuro-endoscope trocars, allowing visualization of the procedure. To aid in tissue and/or fluid removal, the Apollo Generator provides the saline irrigation and vibrational energy to the Wand to ensure the Wand does not become clogged. Aspiration of the tissue and/or fluid is performed by the Apollo Vacuum Pump. Any tissue and/or fluid removed is collected in the Apollo Collection Canister. Activation of saline infusion and vibrational energy is controlled by the Apollo Foot Switch.

1.8 Indications for Use:

The Apollo System is used for the controlled aspiration of tissue and/or fluid during surgery of the Ventricular System or Cerebrum.

1.9 Summary of Non-clinical Data

A literature review was conducted to substantiate the safe and effective performance of the Apollo System, as well as its substantial equivalence to the predicate devices. Current literature was reviewed in relationship to device indications. Review concluded the revised indication for use is appropriate. Additionally, revised labeling was found to have a safety and effectiveness profile that is similar to the predicate devices.

1.10 Summary of Substantial Equivalence

The Apollo System was found to have a safety and effectiveness profile that is similar to the predicate devices.