OCT 2 2012

9 510(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 Cather 025.

9.1 Sponsor/Applicant Name and Address

Penumbra Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502

9.2 Sponsor Contact Information

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

9.3 Date of Preparation of 510(k) Summary

September 6, 2012

9.4 Device Trade or Proprietary Name

Penumbra Pump MAX™

9.5 Device Common/Usual or Classification Name

Apparatus, Suction, Ward Use, Portable, AC-Powered (Product Code: JCX)

9.6 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 Aspiration Pump	Penumbra, Inc Alameda, CA	K051758

9.7 Device Description:

The Penumbra Pump MAX™ is designed to provide general suction for use in hospitals or clinics. The Aspiration Pump operates using AC power and is designed to be portable

if needed. The Aspiration Pump provides vacuum of up to 29 inHg. The pump is available in both 110Vac and 230Vac versions.

The front face of the Aspiration Pump has a display panel with a vacuum gauge, suction regulating valve, and power switch. The pump is used with the available 1000 ml canister / tubing set.

The Aspiration Pump connects to the canister reservoir with a tubing assembly (Penumbra Pump/Canister Tubing), which is provided as an accessory. The Penumbra Pump/Canister Tubing consists of a short tubing segment with an inline filter with connectors on each end to facilitate attachment to the Pump's vacuum port. The tubing is supplied pre-attached to the canister reservoir lid. The Penumbra Pump/Canister Tubing is provided non-sterile and is used outside the sterile field.

9.8 Intended Use:

The Penumbra Pump MAX™ is intended for general suction use in hospitals or clinics.

9.9 Summary of Non-clinical Data:

The physical, mechanical and performance testing of the Penumbra Pump MAX™ demonstrates that the product is substantially equivalent to the currently marketed predicate device.

Pump Design Verification Testing Summary

Attribute	Acceptance Criteria	Results
The Pump shall be compliant with IEC 60601-1 requirements.	100% Pass	Pass: 100%
The Pump shall be compliant with IEC 60601-1-2 requirements.	100% Pass	Pass: 100%
The Pump shall be compliant with ISO 10079-1 requirements.	100% Pass	Pass: 100%
The Pump controls shall be easily identifiable by the User.	100% Pass	Pass: 100%
The pump controls shall be validated for Usability	100% Pass	Pass: 100%
Pump MAX™ should supply uniform vacuum level for an entire case	100% Pass	Pass: 100%
Pump MAX™ will be a durable piece of capital equipment	100% Pass	Pass: 100%
Pump MAX™ should be quiet	100% Pass	Pass: 100%

Attribute	Acceptance Criteria	Results
After use, any blood or clot collected in the canister should be able to be removed for analysis	100% Pass	Pass: 100%
The Canister should have volume reference markings	100% Pass	Pass: 100%
The Canister lid should be backward compatible with the current Aspiration Tubing	100% Pass	Pass: 100%
Canister should be able to withstand maximum pressure delivered by the Pump	100% Pass	Pass: 100%
Canister lid should include a feature to prevent excess fluid from entering the pump.	100% Pass	Pass: 100%

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

OCT 2 2012

Penumbra, Incorporated
% Mr. Seth Schulman
Director, Regulatory Affairs
1351 Harbor Bay Parkway
Alameda, California 94502

Re: K122756
Trade/Device Name: Penumbra Pump MAX™
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: JCX
Dated: September 06, 2012
Received: September 07, 2012

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative 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

Device Name: Penumbra Pump MAX™

Indications for Use:

The Penumbra Pump MAX™ is intended for general suction use in hospitals or clinics.

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)

Neil R Ogden for mxm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122756