K051758/S1

AUG 16 2005

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c)

Submitted by:
Penumbra, Inc.
2401 Merced Street, Suite 200
San Leandro, CA 94577

Contact Person:
Theresa Brander-Allen
VP of Regulatory and Quality
Tel: 510-618-3223
Fax: 510-352-1766
tballen@penumbrainc.com

Date summary prepared: 27 June 2005

Trade Name: Aspiration Pump

Common Name: Powered Suction Pump

Classification Name: 21 CFR Part 878.4780, Apparatus, Suction, Ward Use, Portable, AC-Powered

Device Description:
The Aspiration Pump is designed to provide general suction for use in hospitals or clinics. The Aspiration Pump has an AC power supply and is designed to be portable if needed. The Aspiration Pump provides vacuum of up to 558 mmHg.

Indication for Use:
The Aspiration Pump is intended for general suction use in hospitals or clinics.

Predicate Devices:
Gomco Aspiration Pump, Model 405

Comparison to Predicate Devices to Support Substantial Equivalence Determination:
The Aspiration Pump is made of similar materials and construction to the predicate device. The Aspiration Pump has the same intended use as the predicate device. The Aspiration Pump meets both internal performance requirements and Underwriters Laboratories requirement for electrical safety and electromagnetic compatibility testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2005

Ms. Theresa Brandner-Allen
VP of Regulatory and Quality
Penumbra, Inc.
2401 Merced Street, Suite 200
San Leandro, California 94577

Re: K051758
Trade/Device Name: Penumbra Aspiration Pump
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: BTA, JCX
Dated: August 8, 2005
Received: August 10, 2005

Dear Ms. Brandner-Allen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Barbara Brennd for

Mark N. Melkerson, MS
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Penumbra
stroke intervention

Indications for Use

510(k) Number (if known): K051758

Device Name: Penumbra Aspiration Pump

Indications for Use: The Penumbra Aspiration Pump is intended for general suction use in hospitals or clinics.

Prescription Use _X_ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bueltow for Melkerson

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

Page __ of ___

510(k) Number K051758