K130210

Applicant: Medela AG, Laettichstrasse 4b, CH-6341 Baar, Switzerland
Contact Person: Markus Bütler, Tel +41 (41) 769 51 51; Fax +41 (41) 769 51 00
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Traditional 510(k) Submission for Medela® THOPAZ Suction Pump

MAR 15 2013

Section 5 - 510(k) Summary

This 510(k) summary for the Medela® THOPAZ Suction Pump meets the requirements of 21 CFR 807.92.

1. Sponsor's Name, Address and Contact Person

Sponsor:
Medela AG
Medical Equipment
Laettichstrasse 4b
6341 Baar
Switzerland
Ph: +41 41 769 5151
Fax: +41 41 769 5100

Contact Person
Markus Bütler
VP QM and RA

Date Summary Prepared: January 18, 2013

2. Name of Device

Trade Name: Medela® THOPAZ
Secretion & Surgical Aspirator

Common Name: Powered Suction Pump

Classification Name: PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED)
Classified Class II, per 21 CFR 878.4780

Product Code: BTA

3. Name of the predicate Device(s)

- Medela® THOPAZ, K080212
- Oasis™ Chest Drain, K043140

The Medela® THOPAZ Suction Pump is equipped with the identical technology like other marketed devices. These technological features do not affect safety and effectiveness of the device or the application (pleural and mediastinal drainage).

7. Conclusion

There are no differences in performance or technology which significantly affect the safety and effectiveness of the device or the application (pleural and mediastinal drainage). All conclusions are made by the decision making process according to the recommendations in the "510(k) SE Decision Making Process" document.

The Medela® THOPAZ suction pump has the identical intended uses and, where applicable, the identical technological characteristics and performance data as the predicate devices.

Based upon the information presented in this submission, it is proven that the proposed Medela® THOPAZ powered suction pump is substantially equivalent, safe and effective for the intended use.

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

Medela AG
% Mr. Markus Bütler
Vice President, Quality Management and Regulatory Affairs
Laettichstrasse 4b
Baar, Zug
Switzerland CH-6341

March 15, 2013

Re: K130210
Trade/Device Name: Medela® THOPAZ
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA
Dated: January 18, 2013
Received: January 29, 2013

Dear Mr. Bütler:

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 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

Sincerely yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number (if known):n/a K130210

Device Name: Medela® THOPAZ

Indications for Use:

The Medela® THOPAZ Suction Pump is intended to be used for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials. The Medela® THOPAZ Suction Pump is indicated for all situations where chest drains are applied - especially for thoracic drainage in the pleural and mediastinal cavity in situations such as pneumothorax, after cardiac or thoracic surgery (post-operative), thorax injury, pleural effusion, pleural empyema or other related conditions. The Medela® THOPAZ Suction Pump is intended for use on patients in appropriate care settings.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.03.15 06:44:20 -04'00' for MXM

(Division Sign-off)
Division of Surgical Devices
510(k) Number K130210