DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 25, 2014

Medela AG
Mr. Orlando Antunes
VP Regulatory Affairs
Laettichstrasse 4b
CH-6341 Baar, Switzerland

Re: K141553
Trade/Device Name: Medala ® THOPAZ+
Regulation Number: 21 CFR 878.4780
Regulation Name: Pump, Portable, Aspiration (manual or powered)
Regulatory Class: II
Product Code: BTA
Dated: July 28, 2014
Received: July 31, 2014

Dear Mr. Antunes:

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" (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 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number K141553

Device Name
Medela® THOPAZ+

Indications for Use
Thopaz+ is intended to be used for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials. Thopaz+ 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. Thopaz+ is intended for use on patients in appropriate care settings.

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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**K141553**

# Section 7 - 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
Phone: +41 41 5626671
Fax: +41 41 769 5100

Contact Person
Orlando Antunes
VP Regulatory Affairs

**Summary prepared** 02 June 2014

## 2 Name of Device

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|---|---|
| Trade Name: | **Medela® THOPAZ+**<br>Secretion & Surgical Aspirator |
| Common Name: | Powered Suction Pump |
| Classification Name: | PUMP, PORTABLE, ASPIRATION (MANUAL OR POWERED)<br>Classified Class II, per 21 CFR 878.4780 |
| Product Code: | BTA |

## 3 Name of the unmodified legally marketed device

- Medela® THOPAZ, K130210

Applicant: Medela AG, Laettichstrasse 4b, CH-6341 Baar, Switzerland
Contact Person: Orlando Antunes
Phone/Fax: +41 (41) 561 66 71 / +41 (41) 769 51 00
E-Mail: orlando.antunes@medela.ch


# 4 Device Description

The **Medela® THOPAZ+** suction pump is an innovative secretion aspirator intended to be used for thoracic drainage. Its well-proven membrane system guarantees maximum suction performance and quiet, dependable operation. Additional advantages of the Medela® THOPAZ+ are: User friendliness, patient mobility, simple cleaning and integrated safety features. A comprehensive range of accessories makes the **Medela® THOPAZ+** suction pump ideally suited for thoracic drainage while mobilizing the patient.

The **Medela® THOPAZ+** suction pump is an AC/DC powered, maintenance-free aspirator which incorporates a DC-motor with membrane aggregate power actuation in its housing. A user friendly MMI (man machine interface) guides the user through first installation, change of settings, use, data transfer and alarm handling.

The **Medela® THOPAZ+** suction pump has an electronic measuring and monitoring system for air and fluid being drained with optical and acoustic status display. The device is a dry system, which means that no fluids are necessary for operation. Important information about the course of therapy is displayed digitally and as graphics in the display. These data can be transferred to a PC upon completion of the therapy.

The **Medela® THOPAZ+** suction pump has a suction capacity of 5 liters per minute and a maximum vacuum up to -10 kPa (-75 mmHg). The pump is marked “low flow – low vacuum”.

A variety of reusable and disposable accessories for pleural and mediastinal drainage are available.

# 5 Indications for use

Thopaz+ is intended to be used for aspiration and removal of surgical fluids, tissue, gases, bodily fluids or infectious materials. Thopaz+ 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. Thopaz+ is intended for use on patients in appropriate care settings.

# 6 Summary of Technological Characteristics

The **Medela® THOPAZ+** has the same performance characteristics as the unmodified legally marketed device Medela® THOPAZ. Modifications to the unmodified legally marketed device are outlined in section 12 – Outline of modifications – Justification for Special 510k. 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). The outline of changes in-

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cludes the identification of the changes that indicate submission of a Special 510(k) as required per FDA memorandum #K97-1 "Deciding When to Submit a 510(k) for a Change to an Existing Device". Subsequent verification and validation activities for the applied changes are referenced and evidence is contained within this submission. All modifications to the unmodified legally marketed device are evaluated as part of the risk management as outlined in attachment 16 Risk Management. Documented evidence is contained in this submission.

# 7 Conclusion

With regards to the legally marketed device Medela® THOPAZ, K130210 several minor changes have been implemented and are documented in this Special 510(k) device modification as shortly summarized below.

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| 1. Fixation of bed holder | The new bed holder is optimized to allow fixation of the pump on the hospital bed. To reflect the increasing variety of bed types, the new optimized version of the bed holder is implemented to allow continuous proper fixation of the THOPAZ+ to hospital beds. |
| 2. Sealing of housing | The device is now sealed to prevent from any disinfection agents going into the housing. The additional sealing is only an improvement and the IP classification remains the same as before. Nevertheless it was introduced to enhance resistance against fluids, e.g. disinfectant fluids used. |
| 3. Inclusion of new level PCB in housing | The new sensor is included in the housing which is used for fluid level detection that is now introduced (refer also to change 09). |
| 4. Seal / O-ring (color and shape) | The color of the seal which seals the connection of the canister to the device has been changed to orange and has been slightly adapted in order to prevent undesired removal of the seal.<br><br>In order to improve the detection of a missing seal the color of the seal was changed to orange and the new seal is sticking better to the housing with a slightly adapted geometry. |
| 5. New tubing accessories | New tubing sizes are introduced to the subject device. These sizes extend the range of sizes that has existed for the legally marketed device in order to improve connection to large catheter sizes. |
| 6. Optimization of carry- | As a result of the optimized handle the carrying strap was slightly |

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| ing strap | adapted in diameter and wideness. |
| 7. IFU revised to include information on all changes | Because of all changes applied to the legally marketed device it was necessary to adapt the instructions for use. The new instructions for use generally compromises the same information. Though, it has been complemented with the information for the new level measurement and all other changes discussed in this document. |
| 8. Adapted device PCB | Because of the usage of a new level sensor, some minor changes of the assembly were implemented:<br>- New level sensor power supply<br>- Digital communication interface<br>- Optimization of resistors and capacitors to enhance communication speed |
| 9. Fluid level measurement | In order to measure also the fluid levels resulting from the drainage a new PCB was added. The PCB can measure fluids capacitive through the device wall providing a reliable fluid measurement independent from the fluids consistency (e.g. blood, water, fatty liquids etc.). |
| 10. Device Firmware | The device FW from Thopaz+ is based on the firmware of the legally marketed device THOPAZ, K130210. However in order to implement the fluid measurement the user interface had to be revised. The device firmware controls, checks and regulates all main device functions.<br>Generally, except for the new fluid measurement function, the user interface remains unchanged. All functions regarding regulation of the negative pressure work for both devices.<br>For the new Thopaz+ the firmware had to be adapted mainly in order to show the new fluid amount parameters. None of these changes impact the normal therapy function and the generation of the negative pressure. |
| 11. Color display and key- | In order to include the fluid measurement the device was |

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| pad | equipped with a new slightly bigger color display. The active area is now 73.4X49mm.<br><br>Because of the bigger size of the display the keypad needed to be adapted. However, the keypad still provides the same amount of buttons to approve a good transition from the legally marketed device to Thopaz+. Because of the higher brightness of the new color display an environment sensor was included to the new keypad, which allows to adapt the display brightness according to the environmental brightness. |

None of the modifications alters the Indications for Use in a significant way, nor the fundamental scientific technology, and do not introduce a fundamentally new scientific technology.

We therefore believe that the information presented in this Special 510(k) demonstrates that the product is safe for the patient, user, and bystander and does not raise any new questions regarding safety and effectiveness.