Medela Ag
% Adrienne Lenz
Member
Pathway Regulatory Consulting, LLC
W324 S3649 County Road E
Dousman, Wisconsin 53118

June 9, 2021

Re: K150134
Trade/Device Name: Basic, Dominant Flex, KV-6
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QPB

Dear Adrienne Lenz:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated April 21, 2015. Specifically, FDA is updating this SE because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Cindy Chowdhury, OHT4: Office of Surgical and Infection Control Devices, 240-402-6647, Cindy.Chowdhury@fda.hhs.gov.

Sincerely,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

April 21, 2015

Medela AG
% Ms. Adrienne Lenz
Pathway Regulatory Consulting, LLC
W324S3649 Country Road E
Dousman, Wisconsin 53118

Re: K150134
Trade/Device Name: Basic and Dominant Flex Suction Pumps
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA , MUU, HDB
Dated: January 16, 2015
Received: January 21, 2015

Dear Ms. Lenz:

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 *(if known)*

K150134

Device Name
Basic and Dominant Flex Suction Pumps

Indications for Use *(Describe)*

The Basic Suction Pump is indicated for vacuum extraction, aspiration during flexible endoscopy, and aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system either during surgery or at the bedside. The Basic Pump can also be used to provide the vacuum required for use with cardiac tissue stabilizers used in off-pump coronary artery bypass and for use with epicardial ablation probes.

The Dominant Flex Suction Pump is indicated for vacuum extraction, aesthetic body contouring, aspiration during flexible endoscopy, and aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system either during surgery or at the bedside. The Dominant Flex Pump can also be used to provide the vacuum required for use with cardiac tissue stabilizers used in off-pump coronary artery bypass and for use with epicardial ablation probes.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Medela AG
Basic and Dominant Flex Suction Pumps

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

DATE: January 16, 2015

SUBMITTER:

Medela AG
Lättichstrasse 4b
6341 Baar / Switzerland
Phone +41 (0)41 769 51 51
Fax + 41 (0)41 769 51 00

PRIMARY CONTACT PERSON:

Adrienne Lenz, RAC
Member
Pathway Regulatory Consulting, LLC
T 262-290-0023

SECONDARY CONTACT PERSON:

Orlando Antunes
Vice President Regulatory Affairs
Medela AG

DEVICE:

TRADE NAME: Basic, Dominant Flex

COMMON/USUAL NAME: Powered Suction Pump

CLASSIFICATION NAMES: 21 CFR 878.4780 Powered Suction Pump

PRODUCT CODE: BTA

SECONDARY CLASSIFICATIONS:

System, suction, lipoplasty - MUU, 21 CFR 878.50406
Extractor, vacuum, fetal- HDB, 21 CFR 884.4340

PREDICATE DEVICE(S):

Main Predicate: K130123 Basic and Dominant Flex Suction Pumps

K063336 Medela Dominant 50 Lipo, model 600-570628

K051749 Cobra Surgical System

Octopus Evolution AS 2010, Class 1 510(k) exempt

Urchin Evo Stabilizer, Class 1 510(k) exempt

DEVICE DESCRIPTION:

The **Medela® Basic** and **Dominant Flex** are high vacuum and high flow, AC-powered suction pumps that can be used when large quantities of fluid must be suctioned quickly in the hospital, ambulatory surgery center, clinic, and doctors' practice. Their construction includes a piston and cylinder system which provides strong suction performance and quiet, dependable operation and a microcontroller which is used to control motor speed and the user interface. Additional advantages of the **Medela® Basic** and **Dominant Flex** are user friendliness and simple cleaning.

Medela® Basic and **Dominant Flex** cover the 4 main functions of

- Powerful and high suction capacity
- Rapid vacuum build-up
- Low vibrations and quiet
- Design; smooth surface and easy to use and clean

The **Medela® Basic** provides a fixed airflow of 30 l/m and the **Medela® Dominant Flex** offers the innovative function of selectable airflow of 40, 50 or 60 l/m.

All operating elements for nurses or doctors are located on the front side of both pumps. These include the vacuum gauge, vacuum regulator knob, operating elements and Safety Set. The Safety Set consists of a 0.25l jar, lid and float and prevents an overflow into the pump. The **Medela® Basic** and **Dominant Flex** suction pumps can be operated via capacitive sensors (called "CleanTouch") to turn the pumps on/off. Additionally the Dominant Flex has capacitive sensors for adjusting the flow between 40, 50 and 60 l/m. Both pumps have a knob for the vacuum regulator. The vacuum inside the tubing is displayed on the vacuum gauge. The **Medela® Basic** and **Dominant Flex** use three indicator lights to provide information to the user on the status of the pump. All operating elements for the biomedical technicians are located on the back side. This is where the appliance inlet for plugging in the power cord is located.

Both pumps are available either as rack or portable versions. The rack version can be combined with the trolley to create a mobile version.

A variety of reusable and disposable accessories are available for use with the **Medela® Basic** and **Dominant Flex** suction pumps or are intended to be marketed with these pumps.

INTENDED USE:

The intended use for Medela's Basic and Dominant Flex Suction Pumps is to provide a vacuum source for use during surgery.

INDICATIONS FOR USE:

The Basic Suction Pump is indicated for vacuum extraction, aspiration during flexible endoscopy, and aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system either during surgery or at the bedside. The Basic Pump can also be used to provide the vacuum required for use with cardiac tissue stabilizers used in off-pump coronary artery bypass and for use with epicardial ablation probes.

The Dominant Flex Suction Pump is indicated for vacuum extraction, aesthetic body contouring, aspiration during flexible endoscopy, and aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from wounds or from a patient's airway or respiratory support system either during surgery or at the bedside. The Dominant Flex Pump can also be used to provide the vacuum required for use with cardiac tissue stabilizers used in off-pump coronary artery bypass and for use with epicardial ablation probes.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE

The labeling of the Basic and Dominant Flex has been revised to include the following new indications: aesthetic body contouring (Dominant Flex only) and to provide the vacuum required for use with cardiac tissue stabilizers used in off-pump coronary artery bypass and for use with epicardial ablation probes. The Basic and Dominant Flex Suction Pumps are compared to the previously cleared versions (K130123, main predicate) as well as to the Medela Dominant 50 for aesthetic body contouring (K063336), the Estech Cobra Surgical Systems for the new indication to provide a vacuum source during epicardial ablation (K051749) and the Medtronic Octopus Evolution AS 2010 and Urcin Evo 2020 Tissue Stabilizers (Class 1) to provide vacuum during off-pump coronary artery bypass.

The Basic and Dominant Flex only are providing a vacuum source that is used with ablation probes such asthe Estech System and with cardiac tissue stabilizers such as the Medtronic

stabilizers. The ablation probes and stabilizers do not provide vacuum, but the labelling, specifies the use of an operating room suction source.

The Dominant Flex has equivalent specifications to the Dominant 50 Lipo (K063336) for the aesthetic body contouring indication. The Dominant Flex operates at 0.16 horsepower (hp) which provides equivalent performance to the Dominant 50 Lipo which operates at 0.2 hp.

The Basic and Dominant Flex Suction Pumps use identical technology as the Basic and Dominant Flex Suction Pumps cleared in K130123.

SUMMARY OF NON-CLINICAL TESTS:

The Basic and Dominant Flex Suction pumps comply with voluntary standards for electrical safety, electromagnetic compatibility, and safety of electrically powered suction pumps. The changes to the product labeling for new indications for use did not impact compliance to standards as compared to the pumps cleared in K130123. Non-significant changes made to the Basic and Dominant Flex Suction Pumps since the original clearance were also described. One of these changes affected electromagnetic compatibility and therefore testing to IEC 60601-1-2:2007 was completed.

For the new indications for the Basic and Dominant Flex Suction Pumps, Medela AG has completed bench testing to demonstrate the performance of the pumps in the new applications.

For use for the indication of aesthetic body contouring, a comparison was made between the predicate Dominant 50 Lipo (cleared for aesthetic body contouring (K063336)) with the Dominant Flex to show their equivalence. Then the Dominant Flex was also compared to the HK Liposuction Aspirator Model AP-III which is also cleared for the indication of aesthetic body contouring (K032802). Testing showed equivalent free air flow, vacuum build up, and suctioning capacity of fluids with varying consistencies, including with various cannulas. The density of body fat varies due to the area suctioned and the technique. Sterile water, apple sauce and solidifier mix were used in the testing.

Testing was performed to demonstrate the compatibility of Basic and Dominant Flex in combination with epicardial ablation probes. Testing was conducted with the Estech Cobra Fusion Ablation System (bipolar or monopolar) and demonstrated that when the pump is running the vacuum is maintained at -600 mmHg ± 10%.

Testing was performed to demonstrate the compatibility of Basic and Dominant Flex in combination with cardiac tissue stabilizers used in off-pump coronary artery bypass (OPCAB). Testing was conducted with the Medtronic Octopus Evolution and Urchin Evo Positioners. The test results demonstrate that when the pump is running, the vacuum is maintained at settings of -250 or -400 mmHg for up to 8 hours.

Medela AG
Basic and Dominant Flex Suction Pumps

SUMMARY OF CLINICAL TESTS:

The Basic and Dominant Flex Suction Pumps have not been the subject of clinical testing.

CONCLUSION:

The new indications for use do not change the intended use of the pump, to provide a vacuum source for use during surgery, and do not raise new issues of safety and effectiveness as compared to the main predicate device, cleared in K130123. Verification and Validation testing demonstrated that no adverse effects have been introduced by these differences and that the device performs as intended.

From the results of nonclinical testing described, Medela AG concludes that the Basic and Dominant Flex are substantially equivalent to the legally marketed predicate device.