Modela AG
% Adrienne Lenz
Member
Pathway Regulatory Consulting, LLC
W324S3649 County Road E
Dousman, Wisconsin 53118

June 9, 2021

Re: K170329
Trade/Device Name: Basic, Dominant Flex
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 March 24, 2017. Specifically, FDA is updating this SE Letter 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

March 24, 2017

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

Re: K170329
Trade/Device Name: Basic, Dominant Flex
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA, MUU, HDB
Dated: January 30, 2017
Received: February 2, 2017

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" (21 CFR 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,

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)*
K170329

Device Name
Dominant Flex

Indications for Use *(Describe)*
The intended use of the Dominant Flex suction pump is the creation of a constant vacuum for use in hospitals and clinics.

This vacuum can be used for general suction, to aspirate and remove: surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials and during specific procedures which may include, vacuum extraction, aesthetic body contouring, aspiration during flexible endoscopy, use with cardiac tissue stabilizers during off-pump coronary artery bypass, and 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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."

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)*
K170329

Device Name
Basic

Indications for Use *(Describe)*
The intended use of the Basic suction pump is the creation of a constant vacuum for use in hospitals and clinics.

This vacuum can be used for general suction, to aspirate and remove: surgical fluids, tissue (in-cluding bone), gases, bodily fluids or infectious materials and during specific procedures which may include, vacuum extraction, aspiration during flexible endoscopy, use with cardiac tissue stabilizers during off-pump coronary artery bypass and 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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."

510(k) Summary

K170329

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

DATE: March 22, 2017

SUBMITTER:

Medela AG
Lättichstrasse 4b
6341 Baar / Switzerland
Phone +41 (0)41 561 66 71
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:

Markus Bütler
Director Post Market Surveillance
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):

K150134 Basic and Dominant Flex Suction Pumps

K051758 Penumbra Aspiration Pump

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 in hospitals and clinics.

INDICATIONS FOR USE:

Basic

The intended use of the Basic suction pump is the creation of a constant vacuum for use in hospitals and clinics.

This vacuum can be used for general suction, to aspirate and remove: surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials and during specific procedures which may include, vacuum extraction, aspiration during flexible endoscopy, use with cardiac tissue stabilizers during off-pump coronary artery bypass and epicardial ablation probes.

Dominant Flex

The intended use of the Dominant Flex suction pump is the creation of a constant vacuum for use in hospitals and clinics.

This vacuum can be used for general suction, to aspirate and remove: surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials and during specific procedures which may include, vacuum extraction, aesthetic body contouring, aspiration during flexible endoscopy, use with cardiac tissue stabilizers during off-pump coronary artery bypass, and epicardial ablation probes.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

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

This 510(k) submission revises the labeling of the Basic and Dominant Flex to modify the indications for use. The indications for use have been re-phrased. The indication for aspiration and removal of infectious materials from wounds or from a patient's airway or respiratory support system either during surgery or at the bedside has been modified to remove the locations from which infectious materials are aspirated or removed.

A new indication for general suction has been added for the Basic and Dominant Flex Suction Pumps to cover other general uses. This additional indication does not affect the intended use of the pump to provide suction and is identical to the predicate device, Penumbra Aspiration Pump (K051758).

Several previously cleared indications are now identified as specific procedures: vacuum extraction, aesthetic body contouring, aspiration during flexible endoscopy, use with cardiac tissue stabilizers during off-pump coronary artery bypass and epicardial ablation probes.

There are no differences in the contraindications between the proposed and predicate devices. Additionally, the pumps have identical specifications and use identical technology to the Basic and Dominant Flex were cleared in K150134.

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 K150134. Although not driven by a change to the pump, compliance with the newer 4th edition of IEC 60601-1-2 was demonstrated. Previously submitted testing in K130123 and K150134 are still valid for the general suction and other specific procedures listed in the Basic and Dominant Flex Indications for Use.

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 in hospitals and clinics, and do not raise new issues of safety and effectiveness as compared to the predicate devices. 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.