K130123

510(k) Summary

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

DATE: October 10, 2013

SUBMITTER:

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OCT 11 2013

PRIMARY CONTACT PERSON:

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SECONDARY CONTACT PERSON:

Orlando Atunes
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:

Extractor, vacuum, fetal- HDB, 21 CFR 884.4340

Medela AG
Basic and Dominant Flex Suction Pumps

PREDICATE DEVICE(S):

K021368 Medela "Basic 30" and "Dominant 50" Suction Pumps, Models 037, 057

K011725 Olympus Suction Pump, Model KV-5

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.

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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 Basic and Dominant Flex Suction Pumps are 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.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

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

The Basic and Dominant Flex Suction Pumps use the same fundamental technology as the Basic 30 and Dominant 50 Suction Pumps for most features. Basic and Dominant Flex are similar to the predicate devices in their indications for use. The user interface is also similar to the predicate devices. The main differences are improvements in the housing for easier maintenance and cleaning and the selectable flow feature of Dominant Flex. The table below summarizes the key differences between the Basic and Dominant Flex Suction Pumps and the main predicate devices.

	Basic and Dominant Flex	**Basic 30 and Dominant 50**	**Discussion of Differences**
510(k) Number	---	K021368	
Indications for Use	The Basic and Dominant Flex Suction Pumps are 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 30 and dominant 50 Suction Pumps are indicated for vacuum extraction, 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 patient's bedside.	Equivalent. Dominant 50 was cleared for general suction in K021368. The Olympus KV-5 Suction Pump (K011725) is cleared for the indication for aspiration during flexible endoscopy.

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Basic and Dominant Flex Suction Pumps

	Basic and Dominant Flex		Basic 30 and Dominant 50		Discussion of Differences
Housing and User Interface	Capacitive Touch Sensors which allows housing with all flat surfaces. LED Indicators		On/Off Switch which creates gaps in the housing. LED Indicators		Equivalent. Both devices have similar controls and indicators. There are no gaps/edges around the "buttons" of the Basic and Dominant Flex leading to a full surface for a wipe-off disinfection.
Flow liters/min	30 l/min (Basic) Selectable 40 l/min, 50 l/min, 60 l/min (Dominant Flex)		30 l/min (Basic 30) 50 l/min (Dominant 50)		Equivalent. Other pumps, including the Vacuson 40 and Vacuson 60 (K042943, Reference Device) which was cleared as substantially equivalent to the predicate Basic 30 and Dominant 50 have flows of 40 and 60 liters/min.
Maximum vacuum mmHg/kPa	Basic -675mmHg -90 kPa	Dominant Flex -713mmHg -95 kPa	Basic 30 -638 mmHg -85 kPa	Dominant 50 -675 mmHg -90 kPa	Equivalent. Dominant Flex now offers a slightly higher vacuum.
Flow control	Software is used to change the revolutions per minute (RPM) of the motor allowing the different flow values.		Flow is not adjustable. The different flow rates of the Basic 30 and Dominant 50 were controlled based on the size of the cylinder		Equivalent. Both technologies (changing motor RPM or using different cylinder sizes) achieve the desired flow rates. The Laerdal Suction Unit (K993668) also has electronics to control the flow rate. Their flow rate is coupled with the vacuum level (the higher the vacuum, the higher the flow).

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 following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Software Validation
- Electrical safety and electromagnetic compatibility testing per IEC 60601-1 and IEC 60601-1-2 standards, respectively
- Safety testing per ISO 10079-1 standard for electrically powered suction pumps
- Bench Testing demonstrated that the specifications for vacuum, flow, noise and endurance were met.

SUMMARY OF CLINICAL TESTS:

The Basic and Dominant Flex Suction Pumps have not been the subject of clinical testing. A clinical evaluation of published literature has been conducted for Basic and Dominant Flex Suction Pumps to support the use for the listed indications.

CONCLUSION:

Medela AG considers the Basic and Dominant Flex Suction Pumps to be as safe as, as effective as, and substantially equivalent to the predicate devices.

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

October 11, 2013

Medela AG
% Ms. Adrienne Lenz, RAC
Member
W324 S3649 County Road E
Dousman, Wisconsin 53118

Re: K130123
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, HDB
Dated: September 9, 2013
Received: September 10, 2013

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 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/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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

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

Enclosure

510(k) Number (if known): K130123

Device Name: Basic and Dominant Flex Suction Pumps

Indications for Use:

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Prescription Use_X___ AND/OR Over-The-Counter Use__

(Part 21 CFR 801 Subpart D) (Part 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)

Jiyoung Dang -S