DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 22, 2014

SIMEX Medizintechnik, GmbH
FloSure Technologies LLC
% Mr. Hamid Khosrowshahi
President
P.O. Box 123
Tarrytown, New York 10591

Re: K141255
Trade/Device Name: SIMEX Subglottic Aspiration System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: BTA
Dated: August 19, 2014
Received: August 21, 2014

Dear Mr. Khosrowshahi:

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)*
K141255

Device Name
SIMEX Subglottic Aspiration System

Indications for Use *(Describe)*

The SIMEX Subglottic Aspiration System models cuff M and cuff S are indicated for vacuum suction, extraction, aspiration and removal of surgical fluids, tissue (including bone), bodily fluids or infectious materials from wounds or from patient's airway or respiratory system, either during surgery or at the patient's bedside.

Generally, the SIMEX Subglottic Aspiration System is intended for removing subglottic secretions from the patient's airway above the endotracheal or tracheal cuff using intermittent suction when used in ICU and acute care settings where the duration of mechanical ventilation is limited to a maximum of 4 weeks.

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.

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510(k) Summary

Date Prepared: September 15, 2014

Sponsor and Manufacturer:
SIMEX Medizintechnik, GmbH
Post Box 1207
D-78649. Deisslingen, Germany
FDA Registration Number 3005813597

510(k) Contact:
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PO Box 123
Tarrytown, New York, 10591
Telephone: 914-772-7326
e-mail : hkhosrow@optonline.net

Trade Name: SIMEX Subglottic Aspiration System
Models cuff M and cuff S

Classification: Powered Suction Pump
FDA 21 CFR 878.4780
Class II

Product Code: BTA – Pump, Portable, Aspiration (Manual or Powered)

Predicate Devices:

Medela® Vario 8/18/ci Secretion & Surgical Aspirator System
510(k) K061205 Medela AG
Product Code BTA

SIMEX EX^{200} and EX^{300} Negative Pressure Wound Therapy System
510(k) K113291 SIMEX Medizitechnik GmbH
Product Code OMP

SIMEX Suction Pumps
510(k) K061133 Novaspine LLC
Product Code BTA

Indications for Use:
The SIMEX Subglottic Aspiration System models cuff M and cuff S are indicated for vacuum suction, extraction, aspiration and removal of surgical fluids, tissue (including bone), bodily fluids or infectious materials from wounds or from patient's airway or respiratory system, either during surgery or at the patient's bedside.

Generally, the SIMEX Subglottic Aspiration System is intended for removing subglottic secretions from the patient's airway above the endotracheal or tracheal cuff using intermittent suction when used in ICU and acute care settings where the duration of mechanical ventilation is limited to a maximum of 4 weeks.

Device Description:
The SIMEX Subglottic Aspiration System models cuff M and cuff S are lightweight portable or stationary suction/aspiration pumps for medical suction procedures where secretions, blood and other body fluids must be removed. The SIMEX cuff M and cuff S are designed for the application of intermittent aspiration of fluids which is particularly useful in the aspiration of subglottic secretions. Applications range from hospital, emergency care, and acute care facilities.

These pumps are designed and engineered for the proper and effective aspiration of subglottic secretion via intermittent suction. The pump can be set to operate (aspirate) anywhere from 1-60 seconds and to pause from 1-60 minutes. The factory setting is 10 seconds of aspiration time and 10 minutes of pause time and pressure of 100 mbar vacuum. SIMEX cuff M and cuff S suction pumps remove oral and/or gastric secretions from above the tracheal and or endotracheal tube cuff before they can be aspirated by the patient, using intermittent suction to remove subglottic secretions.

There are two models of the SIMEX Subglottic Aspiration System, Models cuff M and cuff S. The two models differ in their housing and collection canister configuration. Both models have the same overall system operation and software. The moving and electrical components of both models are housed in a molded, compact plastic housing. The units include attachment for an external power supply and/or a battery charger.

Non-Clinical Testing (Bench):
The SIMEX Subglottic Aspiration System cuff M and cuff S are manufactured in accordance with FDA Quality System Regulations and EEC Directive 93/42/EEC Annex IX. Testing for electrical safety was conducted to ensure it meets the requirements for IEC 60601-1-2 including the National Differences for the US. Testing also demonstrated that the pumps meet the electromagnetic interference requirements of the above standards.

Bench testing of the SIMEX Subglottic Aspiration Systems cuff M and cuff S demonstrated that pumps are capable of operating for more than 2000 hours and can adequately perform when tested in a simulated use environment across the operating parameters of the pumps.

Substantial Equivalence:
The SIMEX Subglottic Aspiration System cuff M and cuff S are substantially equivalent to other powered suction pumps used for aspiration of secretions from the patient's airway or respiratory system. The SIMEX Subglottic Aspiration System, like it's predicates is used for aspiration of secretions from a patient's airway or respiratory system. The SIMEX system uses the same basic technology of other similar suction pumps and performs the same function by applying negative pressure to aspirate accumulated materials.

Feature Comparison Chart

	SIMEX Subglottic Aspiration System cuff M and cuff S SIMEX Medizintechnik GmbH		**SIMEX Suction pumps** (K061133) NovaSpine LLC	**Medela® Vario 8/18/ci Secretion and Surgical Aspirator** (K061205) Medela AG	**SIMEX EX^{200} and EX^{300} NPWT pumps** (K113291) SIMEX Medizintechnik GmbH	
Product Code	BTA		BTA	BTA	OMP	
Technology	Vacuum pump transmits negative pressure through a tubing system and collection container and connects to a suction catheter		Vacuum pump transmits negative pressure through a tubing system and collection container and connects to a suction catheter	Vacuum pump transmits negative pressure through a tubing system and collection container and connects to a suction catheter	Vacuum pump transmits negative pressure through a tubing system and collection container and connects to a suction catheter	
Manual (Analog) / Digital Operation	Digital Pressure Gauge and Logic-microprocessor		Manual (analog) Suction Pressure Regulator	Manual (analog) Suction Pressure Regulator	Digital Pressure Gauge and Logic-microprocessor	
Constant/Intermittent Operation	Intermittent		Constant	Constant or Intermittent	Constant or Intermittent	
Intermittent Range (On/Off time)	Programmed to: 1-60 sec On 1-60 min Off		N/A	8 Seconds On 4 Seconds Off 16 Seconds On 8 Seconds Off 32 Seconds Off 16 Seconds Off	Programmed to: 2-10 min On 2-10 min Off	
Max Pressure	300 mbar (225 mmHg)		600 mmHg (801 mbar)	563 mmHg (751 mbar) 68 mmHg (91 mbar)	200 (mmHg) (267 mbar)	
Flow Rate (liters/min)	8 liters/min		18-28 liters/min	8 liters/min – Vario 8 18 liters/min – Vario 18	8 liters/min	
Power (AC/DC, Voltage/Hz)	12 V DC 100 /240 VAC, 50/60 Hz		12 V DC 115 /230 VAC, 50/60 Hz	12 V DC 115 /230 VAC, 50/60 Hz	12 V DC 100 /240 VAC, 50/60 Hz	
Electrical Protection Class	Type BF		Type BF	Type BF	Type BF	
Rechargeable Battery	7.4 V, 4.4 Ah – Lithium – Ion		12V, 2.1 Ah, Ni-MH	12V Ni-MH	7.4 V, 4.4 Ah – Lithium – Ion	
Contains Hydrophobic Microbial Filter	Yes		Yes	Yes	Yes	
Weight (kg)	cuff M	cuff S	3.2 kg – 3.9 kg	5.1 kg	EX^{200}	EX^{300}
	1.2 kg	2.2 kg			1.2 kg	2.2 kg
Intake Hose (mm ID)	cuff M	cuff S	6mm – 10mm	6 mm	EX^{200}	EX^{300}
	4 mm	6 mm			4 mm	6 mm

	SIMEX Subglottic Aspiration System cuff M and cuff S SIMEX Medizintechnik GmbH		**SIMEX Suction pumps** (K061133) NovaSpine LLC	**Medela® Vario 8/18/ci Secretion and Surgical Aspirator** (K061205) Medela AG	**SIMEX EX^{200} and EX^{300} NPWT pumps** (K113291) SIMEX Medizintechnik GmbH	
Collection Container	cuff M	cuff S	Reusable collection containers and disposable collection liners (solidifier available)	Reusable and disposable collection containers and disposable collection liners (solidifier available)	EX^{200}	EX^{300}
	Disposable canister with gelling agent and integrated filter and suction tubing	Reusable (single patient use) outer canister with disposable liner containing gelling agent and integrated filter. Suction tubing provided separately			Disposable canister with gelling agent and integrated filter and suction tubing	Reusable (single patient use) outer canister with disposable liner containing gelling agent and integrated filter. Suction tubing provided separately
Container Volume	cuff M	cuff S			EX^{200}	EX^{300}
	250 cc	1000 cc	1000 cc	1000 cc	250 cc	1000 cc
Carrying Bag for transporting pump	Yes		Yes	Yes	Yes	

Conclusion:
The SIMEX Subglottic Aspiration System Models cuff M and cuff S are substantially equivalent to the commercially marketed predicate devices and do not raise new issues of safety and effectiveness.