K113291 page 1/3

AUG 30 2012

## Summary
## 510(k) Summary of Safety and Effectiveness

### Safe Medical Devices Act of 1990 (SMDA)
### 510(k) Summary

**Date Prepared:** March 19, 2012

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

**510(k) Contact:**
ATTN: Mr. Hamid Khosrowshahi
FloSure Technologies LLC
PO Box 123
Tarrytown, New York, 10591
Telephone: 914-772-7326
e-mail : hkhosrow@optonline.net

**Trade Name:** SIMEX Negative Pressure Wound Therapy Powered Suction Pumps Series:
SIM EX200 and
SIM EX300

**Common Name:** Suction/Aspiration Pump

**Classification:**
Suction/Aspiration Pump
FDA 21 CFR 878.4780
Powered Suction Pump
Class II

**Device Product Code** OMP - Pump, Portable, Aspiration, (Manual or Powered)
Code: OMP (previously BTA or JCX)

**Substantial Equivalency**

| | | |
|---|---|---|
| **MedicaRent Company** | K112458 | Prospera PRO-I, PRO-II and PRO-III |
| **NovaSpine** | K062456 | PRO-I |
| **Kinetic Concepts** | K971548 | AmbuVAC |
| **Medela** | K080357 | Invia Liberty |
| **Blue Sky Medical Group, Inc.** | K042134 | Versatile 1 Wound Vacuum System |

**Indications for Use:**

The SIMEX Negative Pressure Wound Therapy System is indicated for patients that would benefit from a suction device particularly as the device may promote wound healing by removal of wound exudate, debris, and infectious material or for the aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from the patient's airway or respiratory support system. The SIM EX200 and SIM EX300 Negative Pressure Wound Therapy may be used during surgery or at the patient's bedside.

**Device Description:**

The SIMEX Negative Pressure Wound Therapy Powered Suction Pumps Series: SIM EX200 and SIM EX300 are lightweight, self contained, portable battery powered (or line powered), suction pumps for medical procedures where secretions and other body fluids and infectious materials must be removed through the application of continuous or intermittent negative pressure. The pumps are operated through computer software, having help and alarm features. The device is indicted for management of chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts. The pumps may be used at patient's bedside. SIM EX200 and SIM EX300 are suitable for use in either hospitals or long term care facilities and nursing homes.

The SIMEX Negative Pressure Wound Therapy Powered Suction Pumps series is provided in two models, the SIM EX200 and the SIM EX300. Both pumps are powered with rechargeable lithium batteries and include ports for an external power supply and/or battery charger. The pumps can also be externally powered from a 12V automotive battery source. The SIMEX pumps vary in weight from 2.9lbs to 4.9lbs and in size from 90mm x 165mm x 220mm to 130mm x 359mm x 250mm. The SIMEX pumps can be programmed to operate in either continuous or intermittent settings.

The disposable and replacement parts of the SIMEX Negative Pressure Wound Therapy series of pumps include collection canisters, canister liners, pump filters, hoses, connectors and drains (tubing), gauze dressings, and transparent film and drape dressings.

**Non-Clinical Test (Bench):**
The SIMEX SIM EX200 and SIM EX300 series pumps are manufactured in accordance with 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 mentioned standards. The pump's manufacture and quality systems management are in accordance with Quality System Regulations and certified international standards, including ISO 13485.

**Basis For Substantial Equivalence:**

The SIMEX Negative Pressure Wound Therapy Series of pumps SIM EX200 and SIM EX300, like the predicate devices, are portable, powered suction devices. The SIMEX pumps and the predicate devices, particularly the Prospera PRO-I, PRO-II, and PRO-III pumps, have equivalent Indications for Use. **Table 1** below provides a comparison of technological characteristics.

**Table 1 Comparison Summary of Technological Characteristics**

| **Feature** | **Predicate: K112458, PRO-I, PRO-II and PRO-III NPWT pumps** | **SIM EX200 and SIM EX300** |
|---|---|---|
| Dressing System | Gauze based dressing kit with adhesive film drape to create a sealed wound environment | Same as predicate |
| Pressure sensing | Sensors in the unit | Same as predicate |
| Therapy unit | Computer software controlled, battery and AC powered negative pressure wound therapy pumps using both continuous and intermittent operations to remove exudates from the wound to the collection canister | Same as predicate |

The SIMEX Negative Pressure Wound Therapy Suction Pumps Series SIM EX200 and SIM EX300 is substantially equivalent to the commercially marketed predicate devices and does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 30 2012

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

Re: K113291
Trade/Device Name: SIMEX Negative Pressure Wound Therapy Powered Suction Pumps Series SIM EX200 and SIM EX300
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: OMP
Dated: August 20, 2012
Received: August 22, 2012

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

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Erin E. Keith

for Mark Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications for Use Statement

## 510(k) Number:

## Device Name:

**SIMEX Negative Pressure Wound Therapy**
**Powered Suction Pumps**
**Series SIM EX200 and SIM EX300**

## Indication for Use:

The SIMEX Negative Pressure Wound Therapy System is indicated for patients that would benefit from a suction device particularly as the device may promote wound healing by removal of wound exudate, debris, and infectious material or for the aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious material from the patient's airway or respiratory support system. The SIM EX200 and SIM EX300 Negative Pressure Wound Therapy may be used during surgery or at the patient's bedside.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113291