

JAN - 5 2012

K112458

1 of 2

510(k) Summary of Safety and Effectiveness

Date prepared: October 21, 2011

510(k) Owner: Medica-Rents Co LTD
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Owner/Operator #: 1640798

510(k) Contact: Dina L. Weissman, J.D.
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Contract Manufacturer: Simex Medizintechnik, GmbH
Bruckstr. 30/1
Deisslingen-Lauffen, Baden-Wurtetmberg, 78652 Germany

Trade Name: Prospera PRO-I, PRO-II and PRO-III Negative Pressure Wound Therapy System

Common Name: Negative Pressure Wound Therapy Powered Suction Pump

Classification: Powered Suction Pump, 21 CFR 878.4780
Class II, General & Plastic Surgery

Device Product Code: OMP - Pump, Portable, Aspiration, (Manual or Powered)

Substantial Equivalency: Medica Rents Powered Suction Pump PRO-I K062456
(cleared as the NovaSpine Powered Suction Pump PRO-I)

Indications for Use:

The Prospera 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 Prospera Negative Pressure Wound Therapy may be used during surgery or at the patient's bedside and is indicated for home use.

Device Description:

The Prospera PRO Series of Powered Suction Pump is a portable, AC-powered device to be used to remove fluids, including wound exudate, irrigation fluids, and infectious materials from a wound. The pump is operated through computer software, having help and alarm functions. The software settings permit continuous or intermittent negative pressure to be applied for proscribed time periods. The device is indicated 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 a patient's bedside. Some models are portable. The Prospera series of pumps are suitable for use in either a hospital or home, with proper training and supervision.

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The Prospera Negative Pressure Wound Therapy Powered Suction Pump is available in three models. The PRO-I was previously cleared in K062456 and is again included here because a relief valve was added. The PRO-II is a smaller, more portable unit having an integrated disposable canister. Both the PRO-II and PRO-III have a lithium ion battery while the PRO-I has a Nickel-metal Hydride (NiMh) battery. All three models are rechargeable and include a port for an external power supply and/or a battery charger. The pump can also be externally powered from a 12V automotive battery source.

All models provide suction at the rate of 9 liters per minute; have a maximum vacuum of -200 mmHg (negative pressure); weigh between 1.8 and 2.8 kg; and operate in continuous or intermittent modes. Maximum dimensions of the unit are 290mmX359mmX130mm (PRO-I).

Consumable accessory components include collection canisters (rigid or collapsible), hoses, connectors and drains (tubing), and foam or gauze dressings.

The device provides negative pressure wound therapy at a range of pressure settings and removes exudates from the wound site through tubing and microbial filters to a disposable canister. The pumps are compatible with a variety of wound dressing kits, using either gauze or foam dressings.

Summary of Technological Characteristics

Feature	Predicate: K062456, PRO-I NPWT pump	This submission: PRO-II, PRO-III
Dressing system	Foam or gauze based dressing with an adhesive film drape to create a sealed wound environment	Same as predicate
Pressure sensing	Sensors in unit	Same as predicate
Therapy unit	Computer software controlled, battery and AC powered negative pressure pumps using continuous or intermittent modes to remove exudates from the wound to a collection canister	Same as predicate

Non-Clinical Test (Bench):

The Prospera PRO series of pumps is 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 U.S. The pump's manufacture and quality systems management are in accordance with certified international standards, including ISO 13485. Testing was also conducted to verify the changes in the design meet design specifications and demonstrated substantial equivalence to the predicate device, the PRO-I.

Basis For Substantial Equivalence:

In order to demonstrate substantial equivalence, Medica-Rents evaluated the indications for use (unchanged), materials (unchanged), technology (unchanged), product specifications (design control verification and validation conducted), and energy requirements of the device (unchanged). Performance testing and electrical safety has been successfully completed and documented to demonstrate that the modified PRO-I, along with the PRO-II and PRO-III, are substantially equivalent to the previously cleared PRO-I.



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

Medica-Rents Co., Ltd
% Dina L. Weissman, J.D.
Legal and Regulatory Affairs Consultant
P.O. Box 205
Derby, Connecticut 06418

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Re: K112458
Trade/Device Name: Prospera PRO-I, PRO-II and PRO-III Negative Pressure Wound
Therapy
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: December 12, 2011
Received: December 13, 2011

Dear Ms. Weissman:

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.

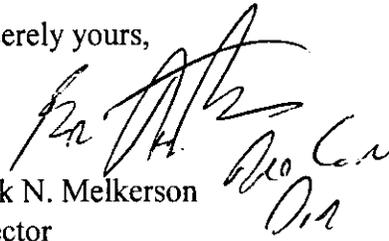
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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,



Mark N. 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: K112458

Device Name:

Prospera PRO-I, PRO-II and PRO-III Negative Pressure Wound Therapy System

Indication for Use:

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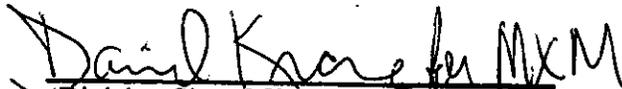
Prescription Use
(Part 21 CFR 801 Subpart D)

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 K112458