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K09 3564

Confidential

510(k) Summary
SVED® WOUND TREATMENT SYSTEM

1. **Name/Address of Submitter:** Innovative Therapies, Inc.
12 Meem Ave., Suite C
Gaithersburg, MD 20877
2. **Contact Person:** Judith Harbour
Director, Regulatory and Quality
866.484.6798 x 105
3. **Date Summary Prepared:** October 26, 2009
4. **Name of Device:** Sved® Wound Treatment System
5. **Classification Name:** Powered Suction Pump
21 CFR 878.4780
Class II
6. **Predicate Device:** ANTLIA I™ Wound Irrigation System
510(k) No.K071301

7. Description of Device

The Sved® Wound Treatment System consists of the identical powered suction pump components and functions as the Svedman® Wound Treatment System, only housed in a smaller, lighter weight plastic enclosure with a built-in placement holder for the 300cc Sved® collection canister. The Svamp™ Wound Dressing components remain the same and are provided in Small, Medium, Large and XL sizes of the polyurethane foam dressing.

8. Indication For Use

The Sved® Wound Treatment System is indicated for patients who would benefit from an AC-powered, portable suction device with battery backup that provides vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The Sved® Wound Treatment System is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts. The specifically designed SVAMP® dressing components are provided for irrigation to a wound with sterile saline or other applicable topical

solutions. During and after irrigation, negative pressure can be applied to assist in the removal of infectious materials or other fluids.

9. Technological Characteristics and Substantial Equivalence

The Sved® Wound Treatment System Unit is smaller in size and weighs less compared to the predicate powered suction pump, yet has the same technological characteristics and identical functions.

10. Conclusion

The substantial equivalence for the Sved® Wound Treatment System is based on the same indications, intended use, and technological features of the predicate device.



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Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-066-0609
Silver Spring, MD 20993-0002

Innovative Therapies, Inc.
% Regulatory Technology Services, LLC
Mr. Mark Job
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K093564
Trade/Device Name: Sved[®] Wound Treatment System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: Class II
Product Code: OMP
Dated: November 16, 2009
Received: November 18, 2009

Dear Mr. Job:

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.

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

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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" (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/cdrh/mdr/> 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/cdrh/industry/support/index.html>.

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

510(k) Number (if known): _____

Device Name: Sved® Wound Treatment System

Indications for Use:

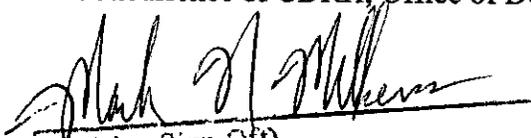
The Sved® Wound Treatment System is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The intended use for the Sved® Wound Treatment System is for patients with chronic, acute, traumatic, subacute and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


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

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