K090635 page 1/2

Special 510k Summary

General Information

1. **Applicant:**

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Great Neck, NY 11021
(t) 516.487.8787
(f) 516.487.7878
www.genadyne.com

APR 2 9 2009

2. **Contact Person:**

Mr. Chien-Ming GOH (Andrew)
Vice President
Genadyne Biotechnologies Inc.
65 Watermill Lane,
Great Neck, NY 11021
Tel: 516-487-8787
Fax: 516-487-7878
Andrew@genadyne.com

3. **Trade/Proprietary Name Including Model Number of Device:**

   Genadyne A4-XLR8 Wound Vacuum System

4. **Common Name or Classification Name (21 CFR Part 807.87) of Device:**

   Powered Suction Pump (21 CFR 878.4780, Product Code OMP)

5. **Class in which Device has been placed:**

   Class II

6. **Reason for Premarket Notification:**

   Introduction of a new device that is a modification of a legally marketed device.

7. **Identification of Legally Marketed Device Which We Claim Substantial Equivalence (Predicate Device):**

   Genadyne A4 Wound Vacuum System (K082676)

8. Compliance with Requirements of the Federal FD&C Act:

The General and Restorative Device Panel (DGRD) has classified this device as Class II, 21 CFR 878.4780

Product Code: OMP

9. Kit Certification and Information:

This device kit is exactly the same as its predicate device (K082676)

10. Description of the Device

The product is a portable suction device that may promote wound healing when used with accessory wound sealing kits.

11. Intended use of the Device

Genadyne A4-XLR8 Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

12. Substantial Equivalence

In establishing substantial equivalence to the predicate device, Genadyne Biotechnologies evaluated the indications for use, material, technology, product specifications, and energy requirements of the system. Performance testing has been completed to demonstrate the safe and effective use of the Genadyne A4-XLR8 Wound Vacuum System for the intended use.

13. Summary of Safety and Effectiveness

Performance testing and device comparison demonstrates that the subject device is substantially equivalent to the predicate device, and is safe and effective for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 29 2009

Genadyne Biotechnologies, Inc.
% Mr. Chien-Ming Goh
Vice President
65 Watermill Lane
Great Neck, New York 11021

Re: K090638
Trade/Device Name: Genadyne A4-XLR8 Wound Vacuum System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: OMP
Dated: April 20, 2009
Received: April 23, 2009

Dear Mr. Goh:

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090638

Device Name: Genadyne A4-XLR8 Wound Vacuum System

Indications For Use:

The Genadyne A4-XLR8 Wound Vacuum System is indicated for use in patients who would benefit from negative pressure wound therapy particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

Prescription Use ___X__ **(Per 21 CFR 801 Subpart D)** 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)

David Krause for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K090638