510(k) Summary
807.92(c)

JUN 29 2010

SPONSOR **807.92(a)(1)**

Company Name: Genadyne Biotechnologies, Inc.

Company Address: 65 Watermill Lane
Great Neck, NY 11021

Telephone: 800.208.2025
Fax: 516.487.7878

Contact Person: Chien-Ming Goh

Summary Preparation Date: June 17, 2010

DEVICE NAME **807.92(a)(2)**

Trade Name:	A4-XLR8 Foam Dressing
Common/Usual Name:	Foam Dressing
Classification Name:	Negative Pressure Wound Therapy Powered Suction Pump and Accessories
Regulation Number:	21 CFR 878.4780
Product Code:	OMP
Device Class:	Class II
Panel:	General & Plastic Surgery

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
Smith & Nephew, Inc.	Renasys™-F NPWT Foam Dressing	K082211

DEVICE DESCRIPTION **807.92(a)(4)**

Genadyne A4-XLR8 Foam Dressing is manufactured using a reticulated flexible polyether and polyurethane hydrophobic foam material. The single-use dressing is housed in a Tyvek/Mylar Peel Pouch which is sterilized using EtO.

Genadyne A4-XLR8 Foam Dressing is available in three sizes; 1) small, 2) medium and 3) large.

DEVICE INTENDED USE **807.92(a)(5)**

Genadyne A4-XLR8 Foam Dressing is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) to deliver negative pressure wound therapy to the wound. Genadyne A4 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

A4-XLR8 Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Comparative Bench

Caution: Federal law restricts this device to sale by or on the order of a physician.

NONCLINICAL AND CLINICAL TEST **807.92(b)**

Test	Standard	Results
L929 MEM Elution Test - ISO	ISO 10993-5	Reticulated PE/PU, is considered non-cytotoxic and meets the requirements of the Elution Test defined in ISO 10993-5 guidelines.
L929 MEM Elution Test - ISO	ISO 10993-5	Reticulated PE/PU, is considered non-cytotoxic and meets the requirements of the Elution Test defined in ISO 10993-5 guidelines.
L929 MEM Elution Test - ISO	ISO 10993-10	Reticulated PE/PU, is considered non-cytotoxic and meets the requirements of the Elution Test defined in ISO 10993-5 guidelines.
Kligman Maximization Test - ISO	ISO 10993-10	Based on the criteria of the protocol, a Grade I sensitization rate is not considered significant and the test article meets the requirements of the ISO 10993-10 guidelines.
Intracutaneous Injection Test - ISO	ISO 10993-10	Based on the criteria of the protocol, the test article is considered a negligible irritant and meets the

		requirements of the ISO 10993-10 guidelines.
Kinetic Limulus Amebocyte Lysate Test (LAL)	USP 32, NF 27:2009	The test article contains 0.00689 EU/mL. The correlation coefficient for the linear regression was calculated to be -0.999.
Inhibition and Enhancement Testing, LAL Kinetic Method	USP 32, NF 27:2009	The correlation coefficient for the linear regression was calculated to be -0.999 for standard curve, -0.996 for sample 1 and -0.997 for sample 2 and -0.998 for sample 3. There was no inhibition or enhancement present in the test article.
Bacteriostasis & Fungistasis / Direct Transfer	USP 32, NF 27:2009	The test article is considered non-bacteriostatic and non-fungistatic, according to the USP guidelines.
Bioburden Validation – Exhaustive Recovery	ANSI/AAMI/ISO 11737-1: 2006	The percent recovery was 100% and the recovery factor was 1 using the exhaustive recovery method.
Accelerated Aging	ASTM F1980-07	At the time of this filing 4-months of real-time testing has been completed
Residual EtO, ECh, and EG	ISO 10993-10	• Ethylene Oxide – Not Detected • Ethylene Chlorohydrin – Not Detected • Ethylene Glycol - 1.18 mg, 1.71 mg, 1.43 mg, 1,65 mg, 1.34 mg, 1.31 mg
Comparative Bench Testing of Subject Device Vs Predicate Device	In-house	Based on the comparative bench test it was established that the A4-XLR8 Foam Dressing Kit is substantially equivalent to the Renasys F NPWT Dressing Kit.*

***OVERVIEW OF COMPARATIVE BENCH TEST**

To ensure that the Genadyne A4-XLR8 Foam Dressing Kit is substantially equivalent to the Smith and Nephew Renasys F NPWT Foam Dressing Kit, Genadyne collected data on 3 different conditions during the bench test to demonstrate that under a vacuum environment and at different set levels of vacuum pressure, the foam performed exactly as expected and there were no unexpected outcomes during the tests.

The following tests were conducted:

1. Dimensions were recorded before and after the 72 hours bench test. The results demonstrated after undergoing long periods of suction pressures both dressings appeared unchanged.
2. Suction pressures were recorded to determine the variation in suction pressures between the Genadyne A4Foam Dressing and the Smith & Nephew Foam. It was determined that the difference in suction pressures between the two dressings is ± 5mmHg. It was also noted that pressure distribution appeared to be uniform across both dressings.
3. Fluid removal rates were recorded to determine the wound exudate removal rate between the Genadyne A4 Foam Dressing and the Smith & Nephew Foam Dressing using plasma to simulate wound exudate. Suction was continuous for the entire 72 hour study. Fluid removal rate was found to be substantially equivalent.

SUBSTANTIAL EQUIVALENCE **807.92(b)(3)**

In establishing substantial equivalence to the predicate device, Genadyne Biotechnologies evaluated the indications for use, material, technology, and product specifications of the product. Performance testing has been completed to demonstrate the substantial equivalence of the Genadyne A4-XLR8 Foam Dressing for its indications for use.

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

Genadyne Biotechnologies, Inc.
% Smith Associates
E.J. Smith
1468 Harwell Avenue
Crofton, Maryland 21114

JUN 29 2010

Re: K092992
Trade/Device Name: A4-XLR8 Foam Dressing
Regulation Number: 21 CFR 878.4780
Regulation Name: A4-XLR8 Foam Dressing
Regulatory Class: II
Product Code: OMP
Dated: June 1, 2010
Received: June 1, 2010

Dear E.J. Smith:

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

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Indications for Use

510(k) Number (if known): _____

Device Name: A4-XLR8 Foam Dressing

Indications for Use:

Genadyne A4-XLR8 Foam Dressing is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) to deliver negative pressure wound therapy to the wound. Genadyne A4 Wound Vacuum System is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by the removal of excess exudates, infectious material and tissue debris.

A4-XLR8 Foam Dressing is appropriate for use on the following wounds:

- Pressure ulcers
- Diabetic/Neuropathic Ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Post-operative and dehisced surgical wounds
- Skin flap and grafts

Caution: Federal law restricts this device to sale by or on the order of a physician.

(Check appropriate designation below)

Prescription Use ___X___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MXM

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

510(k) Number K092992