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510(k) Summary
807.92(c)

JUL 30 2012

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

Company Name:	Kevo Medical Supplies
Company Address:	3588 Plymouth Rd. Ann Arbor, MI 48105
Telephone:	734.274.0020
Fax:	734.327.0626
Contact Person:	Dr. John Nanos
Summary Preparation Date:	July 22ND, 2012

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

Trade Name:	Kevo NPWT- αHemo30 Foam Dressing Kit
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)**

Company	Brand Name	510(k) Number
Genadyne Biotechnologies, Inc.	A4-XLR8 Foam Dressing	K092992

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

The Kevo NPWT- αHemo30 Foam Dressing Kit 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.

The Kevo NPWT- αHemo30 Foam Dressing Kit is available in three sizes; 1) small, 2) medium and 3) large:

Small: 100mm x 80mm x 30mm
Medium: 125mm x 190mm x 30mm
Large: 150mm x 250mm x 30mm

DEVICE INTENDED USE 807.92(a)(5)

Kevo NPWT- αHemo30 Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) to deliver negative pressure wound therapy to the wound. Kevo NPWT- αHemo30 Foam Dressing Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of excess exudates, infectious material and tissue debris.

Kevo NPWT- αHemo30 Foam Dressing Kit 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 Flaps and Grafts

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

PREDICATE PRODUCT COMPARISON TABLE 807.92(a)(6)

Parameters	Kevo Medical Supplies, Inc.	Genadyne Biotechnologies, Inc.
510(k)		K092992
Foam Dressing Composition	Reticulated flexible polyether based polyurethane foam	Reticulated flexible polyether based polyurethane foam
Foam Dressing Code	Identical (A30M)	Identical (A30M)
Foam Manufacturer	Crest Foam Industries	Crest Foam Industries
Foam Converter/Kitter	Keystone Solutions Group	Keystone Solutions Group
Processing and Sterilization Methods	Identical	Identical
Hydrophobic	Yes	Yes
Sizes	Small, Medium, Large	Small, Medium, Large
For use with negative pressure wound therapy (NPWT)	Yes	Yes
Sterile	Yes	Yes
By Prescription Only	Yes	Yes
Use Environment	Acute, Extended and Home Care Settings by Healthcare Professionals	Acute, Extended and Home Care Settings by Healthcare Professionals

CLINICAL AND NONCLINICAL TESTS 807.92(b)

Overview Of Comparative Bench Tests 807.92(b)(1)

To ensure that the Kevo NPWT- αHemo30 Foam Dressing Kit is substantially equivalent to the Genadyne A4-XLR8 Foam Dressing Kit, Kevo collected data on 3 different conditions during the bench test to demonstrate that under a vacuum environment and at different set levels of negative vacuum pressure, the foam performed exactly as expected and there were no unexpected outcomes during the tests.

The following bench tests were conducted:

1. Dimensions were recorded before and after the 72 hour bench test. The results demonstrated after undergoing long periods of suction pressures both predicate and Kevo dressings appeared unchanged.
2. Suction pressures were recorded to determine the variation in suction pressures between the Kevo NPWT- αHemo30 Foam Dressing Kit and the Genadyne A4-XLR8 Foam Dressing Kit. It was determined that the difference in suction pressures between the two dressings is <+/-5mmHg. It was also noted that the pressure distribution appeared to be uniform across both dressings.
3. Fluid removal rates were recorded to determine the wound exudate removal rate between the Kevo NPWT- αHemo30 Foam Dressing Kit and the Genadyne A4-XLR8 Foam Dressing Kit using plasma to simulate wound exudate. Suction was continuous for the entire 72 hour study. Fluid removal rate was found to be substantially equivalent.

Additional tests were performed to further validate the substantial equivalence of the Kevo NPWT- αHemo30 Foam and the predicated Genadyne A4-XLR8 Foam during its intended use*:

4. Foam Comparisons under constant negative pressure (125mmHg) using the Genadyne A4 wound Vacuum over 72 hours.
5. Foam Comparisons under variable negative pressure (150mmHg, 0mmHg) using the Genadyne A4 wound Vacuum over 72 hours.
6. Foam Comparisons using optical measurement of cell size.

* Synthetic blood O+ (code 70-016) from Carolina Biological was used as a replacement for wound exudate.

Summary of Biocompatibility Compliance Tests 807.92(b)(2)

- ISO 10993-5 L929 MEM Elution Test
- ISO 10993-10 Intracutaneous Injection Test
- ASTM F756-08 Hemolysis – Rabbit Blood – ASTM Indirect Contact
- ISO 10993-10 Kligman Maximization Test

Summary of Sterilization Compliance Tests 807.92(b)(2)

- ISO 10993-7 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals
- USP 32 NF 27, 2009 <85> Bacterial Endotoxins Test, Guidelines on Validation of the Limulus Amebocyte Lysate Test as an End-Product
- ISO 10993 -1 Rabbit Pyrogen Test
- ISO11137-1:2006 Sterilization of Health Care Products Radiation – Part 1: - Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices with Sponsor Specifications.
- ISO 11737-1 2006: Sterilization of Health Care Products – Microbiological Methods – Part 1: Determination of the Population of Microorganism on Products
- ANSI/AAMI/ISO 11737-2:1998 – Sterilization of Medical Devices – Microbiological Methods – Part 2 – Test of Sterility Performed in the Validation of a Sterilization Process.
- USP 32 NF, 2009 <71> Sterility Tests
- ISO 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories
- ASTM F1980-07 Guide for Accelerated Aging of Sterile Medical Devices

SUBSTANTIAL EQUIVALENCE 807.92(b)(3)

In establishing substantial equivalence to the predicate device, Genadyne A4-XLR8 Foam Dressing Kit, Kevo Medical evaluated the indications for use, material, technology, and product specifications for the product. Performance testing has been completed to demonstrate the substantial equivalence of the Kevo NPWT- αHemo30 Foam Dressing Kit 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

JUL 30 2012

Kevo Medical Supplies
% Smith Associates
Mr. E.J. Smith
Consultant
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K113199
Trade/Device Name: The Kevo NPWT-αHemo30 Foam Dressing Kit
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered sunction pump
Regulatory Class: Class II
Product Code: OMP
Dated: June 18, 2012
Received: June 18, 2012

Dear Mr. 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

Indications for Use Form

Indications for Use

510(k) Number (if known): K113199

Device Name: The Kevo NPWT- αHemo30 Foam Dressing Kit

Manufactured For:
Kevo Medical Supplies
3588 Plymouth Rd.
Ann Arbor, MI 48105

Indications for Use:

Kevo NPWT- αHemo30 Foam Dressing Kit is intended to be used in conjunction with the Genadyne A4 Wound Vacuum System (K082676) to deliver negative pressure wound therapy to the wound. Kevo NPWT- αHemo30 Foam Dressing Kit is indicated for patients who would benefit from a suction device, particularly as the device may promote wound healing by removal of excess exudates, infectious material and tissue debris.

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

Prescription Use ___√____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

David Krause for MM

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

510(k) Number K113199