K080275

OCT 09 2008

510(k) Summary

Submitter:	Kalypto Medical 6393 Oakgreen Avenue Hastings, MN 55033
Contact Person:	John Buan, Vice President of Product Development Phone (612) 703-1204, Fax (763) 287-3836
Date Prepared:	August 14, 2008
Trade Name:	NPD 1000 Negative Pressure Wound Therapy System
Classification:	Powered Suction Pump Class II 21 CFR 878.4780
Product Code:	~~BTA~~ JCX
Predicate Device(s):	The subject device is equivalent to the following device: • V.A.C. Therapy Systems-ActiV.A.C. Therapy Unit M: K063692 • Boehringer Laboratories Suction Pump System: K060277
Device Description:	The NPD 1000 Negative Pressure Wound Therapy System includes a small, portable, low powered, battery operated electromechanical pump used with an accessory wound dressing. The system uses controlled negative pressure (vacuum) to remove exudates, which may promote wound healing.
Intended Use:	The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.
Functional and Safety Testing:	To verify that the device design met its functional and performance requirements, representative samples of the device underwent functional and mechanical testing, EMC testing in accordance with IEC 60601-1-2:2001 and electrical safety testing in accordance with UL 60601-1:2006.
Conclusion:	Kalypto Medical considers the NPD 1000 Negative Pressure Wound Therapy System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Kalypto Medical
% Mr. John Baun
6393 Oakgreen Avenue
Hastings, Minnesota 55033

Re: K080275
Trade/Device Name: NPD 1000 Negative Pressure Wound Therapy System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: August 14, 2008
Received: August 15, 2008

Dear Mr. Baun:

This letter corrects our substantially equivalent letter of October 9, 2008.

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 (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); 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.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
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): K080275

Device Name: NPD 1000 Negative Pressure Wound Therapy System

Indications for Use:

The NPD 1000 Negative Pressure Wound Therapy System is a portable, low-powered, battery-operated suction pump intended for the application of suction to remove a small amount of fluid from the wound bed including wound exudate and infectious material which may promote wound healing.

Prescription Use __X__ (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)

for mkm

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

510(k) Number K080275