DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Smith & Nephew, Inc.
% Ms. Laura Krejci
970 Lake Carillon Drive, Suite 110
St. Petersburg, Florida 33716

Re: K042134
Trade/Device Name: Versatile 1 Wound Vacuum System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: August 4, 2004
Received: August 9, 2004

Dear Ms. Krejci:

This letter corrects our substantially equivalent letter of November 15, 2004.

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): K042134

Device Name: Versatile 1 Wound Vacuum System

Indications for Use:

The Versatile 1 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing or for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids, or infectious materials from a patients airway or respiratory support system either during surgery or at the patients bedside.

Nilsa Ogden for CMW

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

510(k) Number K042134

Prescription Use ___XX___ (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)

510(k) Summary

I. Device name: Versatile 1 Wound Vacuum System (Assisted Drainage Device) (V1 WVS)

II. Classification Name: Powered suction Pump (per 21 CFR 878.4780)

III. Substantial Equivalence V.A.C.® Plus 510(k) No. 945062
Medela Vario 510(k) 983552

IV. Device Description

The BlueSky Versatile 1 WVS is a portable suction device that can be powered by an internal battery pack, wall current or 12 Volt input via optional cigarette lighter adaptor. The pump can be used for removal of surgical fluids, tissue, gases, bodily fluids or infected materials during surgery or from a patients airway or respiratory support system. The pump can also be used to create localized topical negative pressure when used with the Chariker-Jeter® accessory kits to promote wound healing and drainage of fluids and infected materials from the wound into a disposable or reusable canister.

The BlueSky versatile 1 Wound Vacuum System (V1 WVS) consists of a medium sized housing that contains a vacuum pump and control system with a location for a fluid canister system. Accessories include are a vehicle power adaptor and a Mobil Stand. A variety of disposables are available from a number of medical device manufacturers depending on the pump application. For the expanded indication of use for wound healing the Chariker -Jeter® accessory kits would be available from BlueSky Medical. This kit consists of individually reviewed medical components that have added instructions for use.

The Versatile 1 Wound Vacuum system is an ideal pump for military use and triage use. By combining a unit that can be used for wound resolution as well as tracheal use or for use in the operating theatre a minimum of products can be used for maximum versatility. The BlueSky V1 WVS is 15 inches by 11.2 inches by 6.7 inches and weighs 11.2 pounds. The battery will last for 30-45 minutes when not plugged in. the Pump can additionally be powered by a 12 volt source such as a cigarette lighter adaptor.

Switching the power switch to either continuous or intermittent suction turns on the pump. Pressing inwards on the suction control knob and then turning the knob in the desired direction adjust the level of suction. The knob will lock when it is not pressed to avoid accidental changes. The operator will view the suction gauge and when proper suction is reached the knob can be released.

Canisters

The pump includes a 250ml reusable polysulfone canister that can be autoclaved. The canister includes a mechanical overflow float to prevent backups into the pump itself. The canister can be autoclaved in a standard hospital autoclave for 134 degrees Celsius for 10 minutes.
The pump also includes a 800ml liter disposable canister that has a mechanical overflow float. This canister is non-sterile and is designed by be discarded when full or partially full.

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Http://www.blueskymedical.com • Email:Info@blueskymedical.com

BlueSky Medical

Single Use Disposables

Marketed as part of the V1 Wound Vacuum System is a disposable kit. This kit is named after the pioneers in the field Katherine Jeter and Dr. Mark Chariker who popularized this technique of wound drainage, which caused wounds to heal more rapidly. "From the days of drainage through ostomy pouches to the current use of suction systems there has evolved a closed suction system incorporating moist wound management principals with the benefits of an inert silicone drain to maximize wound healing[1]"

The Chariker-Jeter wound vacuum system accessory kit. These kits consist of products from existing manufacturers that have met the regulatory requirements of the FDA. They include an additional set of instructions for use. The Kits include:

1. Silicone or Wound drain
2. Connecting tubing
3. Impregnated gauze
4. Gauze fill Material
5. Polyurethane Cover dressing

Indications for Use

The Versatile 1 Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing or for aspiration and removal of surgical fluids, tissue (including bone), gases, bodily fluids or infectious materials from a patients airway or respiratory support system either during surgery or at the patients bedside.

Contraindications for Wound Healing Application

The V1 WVS is contraindicated for the following reasons for Wound treatment

Presence of Necrotic tissue
Untreated Osteomyeltitis
Malignancy (except terminal patients for quality of life issues)
Untreated malnutrition
Use on exposed arteries, veins, or organs

Precautions:

Patients on anticogagulations or difficult hemostatis
Non-Compliant patients

General Precautions for all indications for use: Health care provider must evaluate patient to insure that use of V1 WVS is an appropriate use for the patient.

[1] Effective Management of Incisional and Cutaneous Fistulae With Closed Suction Wound drainage Mark E. Chariker MD, Katherine F. Jeter, Ed.D. Et et. al. Contemporary Surgery Vol 34 June 1989 P9 59-63

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