

FEB 5 2007

K061919

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## 510(k) Summary

### General Information

**Submitters Name/Address:** BlueSky Medical Group, Inc.  
5924 Balfour Ct., Suite 102  
Carlsbad, CA 92008

**Establishment Registration Number:** 2032666

**Contact Person:** Jasper Benke

**Phone Number:** (760) 603-8130

**Date Prepared:** June 30, 2006

### Device Description

**Trade Name:** Versatile 1 EZCare™ Wound Vacuum System

**Generic/Common Name:** Suction Pump and Accessories

**Classification Name:** Powered Suction Pump (21 CFR 878.4780, Product Code BTA)

### Predicate Device Information

Versatile 1™ Wound Vacuum System cleared originally in K042134 (November 15, 2004) and amended in K052456 (November 4, 2005).

### Product Description

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

### Intended Use

The Versatile 1 EZCare™ Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

### Substantial Equivalence

In establishing substantial equivalence to the predicate device, BlueSky Medical evaluated the indications for use, materials, technology, product specifications, and energy requirements of the system. Performance testing has been completed to demonstrate the safe and effective use of the Versatile 1 EZCare™ Wound Vacuum System for the intended use.

### 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.



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: K061919  
Trade/Device Name: Versatile 1 EZCare™ Wound Vacuum System  
Regulation Number: 21 CFR 878.4780  
Regulation Name: Powered Suction Pump  
Regulatory Class: II  
Product Code: OMP  
Dated: January 18, 2007  
Received: January 19, 2007

Dear Ms. Krejci:

This letter corrects our substantially equivalent letter of February 5, 2007.

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

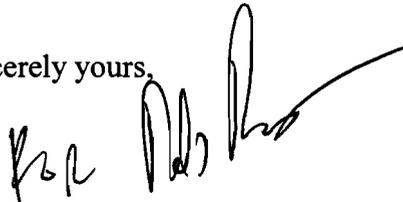
Page 2 - Ms. Laura Krejci

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: K061919

Device Name: Versatile 1 EZCare™ Wound Vacuum System

**Indications for Use:**

The Versatile 1 EZCare™ Wound Vacuum System is indicated for patients who would benefit from a suction device particularly as the device may promote wound healing.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

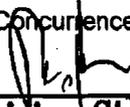
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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