JUN - 1 2004

K032983
510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k): SciVolutions, Inc.
268 Tosca Dr.
Stoughton, MA 02072

Phone: 781-344-3211
Fax: 781-344-9203

Contact Person: Alan Nash

Date of Summary: May 14, 2004

Trade Name: SciVolutions Antibacterial Gentle Care Bandages

Classification Name: Tape and bandage, Adhesive (with disinfectant)

Predicate Device:

K020318 SciVolutions Various Antibacterial Bandages

Indications for Use:

SciVolutions Antibacterial Gentle Care Bandages are to be applied to the skin for topical application for minor cuts and scrapes.

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510(k) Summary

Device Description

The Antibacterial Gentle Care Bandages uses the identical BZC antibacterial pad as on our previously cleared predicate device under K020318. Only the backing (non-woven) is slightly different providing a higher water vapor permeability and soft feel.

Antibacterial Gentle Care Bandages

Non-woven skin color treated hydrophobic backing (Latex Free)

Central pad: High absorption capacity, covered with an anti adherent polyethylene veil, helping to keep it from sticking to the wound, impregnated with 1% benzalkonium chloride solution.

Encased in Latex Free Kraft Paper Cold Sealed to make a envelope wrapper

Sizes: .75" x 3" / 1" x 3"

Uses: Gentle Care 25

In mm-inch	Backing (mm-Inch)	Pad in mm
20x72- 0.75x3	20x72 - 0.75x3	10.8x25
25x72 - 1x3	25x72 - 1x3	13.6x25

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2004

SciVolutions, Inc.
c/o Mr. Arthur J. Ward
RMS, Inc.
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K032983
Trade/Device Name: SciVolutions, Inc. Antibacterial Gentle Care Bandages
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 15, 2004
Received: April 26, 2004

Dear Mr. Ward:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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 begin 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 (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K032983

Indications for Use

510(k) Number (if known): K032983

Device Name: SciVolutions, Inc. Antibacterial Gentle Care Bandages

Indications For Use:

SciVolutions Antibacterial Gentle Care Bandages are to be applied to the skin for topical application for minor cuts and scrapes.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C Provost

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

510(k) Number K032983