1/51 1/2

510(k) SUMMARY
K082208

Regulatory Correspondent: Regulatory and Marketing Services (RMS).
962 Allegro Lane
Apollo Beach, FL 33572
Phone: (813) 645-2855
Fax: (813) 645-2856
awconsltng@aol.com

DEC 0 1 2008

Submitter of 510(k): SciVolutions
2260 Reaford Ct
Gastonia, NC 28052
USA

Phone: 704-853-0100
Fax: 704-853-0400

Contact Person: Alan Nash

Date of Summary: 11/26/08

Trade/Proprietary Name: Doctors Choice slow healing Bandage with Spray on Remover

Classification Name: Dressing, Wound, Hydrophilic

Product Code: NAC

Intended Use:

The Doctors choice bandage with spray on remover is intended for prescription use in the local management of pressure sores as prescribed by a medical practitioner.

Device Description:
The SciVolutions, Doctors Choice slow healing bandage is comprised of three products. The first is a premium gauze bandage with a non-stick net bottom side and a hydropholic breathable, waterproof polyurethane film membrane top side. The second device is a non-stick hydrocolloid bandage with the same polyurethane film membrane top side. Both of these bandage types are packaged for general use or diabetic use, with the only difference being the carton and carton labeling. The third product is the spray on remover, which

K082204/5 2/2

may be used with both products. Those products are in FDA classification code NAC, which is Class 1 and 510(k) exempt. Due to the product modifications and the addition of the spray on remover this 510(k) is being submitted.

Predicate Device:
SciVolutions Gentle Care Bandage – K032983
Algoplaque Film Extra Thin Hydrocolloid Dressing – K974348
3M Tegasorb Thin Hydrocollide Dressing – K982892
DuoDerm Extra Thin CGF Dressing - K973716

Substantial Equivelance:
The Scivolutions Doctors Choice Slow Healing Bandage with Spray on Remover is a Class 1 device which is available in both general purpose and diabetic dressing packaging. The dressing and spray on remover have been tested and the device is considered substantially equivalent to the predicate. This device does not contain any antibacterial agent as our predicate K032983.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 1 2008

SciVolutions
% Regulatory and Marketing Services
Mr. Alan Nash
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K082208
Trade/Device Name: Doctors Choice slow healing Bandage with Spray on Remover
Product Code: NAC
Dated: November 12, 2008
Received: November 17, 2008

Dear Mr. Nash:

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 Center for Devices and Radiological Health's (CDRH's) 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/industry/support/index.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

K082208 1/1

Indications for Use

510(k) Number (if known): K082208

Device Name: Doctors Choice slow healing Bandage with Spray on Remover

Indications for Use:

The Doctors choice bandage with spray on remover is intended for prescription use in the local management of pressure sores as prescribed by a medical professional.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nick Pyle for mkm

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

510(k) Number K082208