K082993

DEC 19 2008

Premarket Notification Summary

Submitted by: Adhezion Biomedical
506 Pine Mountain Road
Hudson, NC 28638
Phone: 828-728-6116

Contact Person: Richard G. Jones
Sr. Vice President
Phone: 610-431-2398
Email: Rjones@Adhezion.com

Date of Summary: October 3, 2008

Device Trade Name: SurgiSeal Topical Skin Adhesive

Common or Usual Name: Topical Skin Adhesive

Classification Name: Tissue Adhesive
Product Code: MPN

Predicate Device: Dermabond High Viscosity Topical Skin Adhesive

Device Description: SURGISEALTM Topical Skin Adhesive is a sterile, professional liquid skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. Each applicator consists of a thermoformed blister tray with a heat sealed lid with an attached applicator sponge tip. This applicator tray with sponge tip is contained in an outer Tyvek pouch.

When SURGISEAL is applied to the skin, it polymerizes in minutes.

Indications for Use: SURGISEAL is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations.

SURGISEAL may be sued in conjunction with, but not in place of, deep dermal sutures.

Substantial Equivalence: SurgiSeal is substantially equivalent to Dermabond. Both use the same active ingredient, 2-Octyl Cyanoacrylate, equivalent in the ASTM Standardized Tests for Adhesion, ISO10993 Biocompatibility Tests for Safety and Animal Test for effect on healing.

Other Testing: SurgiSeal was evaluated in tests to establish a performance profile in accordance with the Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin. The Bench Tests, with Dermabond as control, showed results comparable. One test, Moisture Vapor Transmission Rate, showed higher results which suggest greater transmission of moisture and oxygen to the wound that has the potential to provide a faster healing rate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Adhezion Biomedical
% Mr. Richard G. Jones
Senior Vice President
506 Pine Mountain Road
Hudson, North Carolina 28638

DEC 19 2008

Re: K082993
Trade/Device Name: SurgiSeal™ Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010 (a)
Regulation Name: Tissue adhesive for topical approximation of skin
Regulatory Class: II
Product Code: MPN
Dated: October 3, 2007
Received: October 7, 2007

Dear Mr. Jones:

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

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): K082993

Device Name: **SurgiSeal ™Topical Skin Adhesive**

Indications For Use: **SurgiSeal ™Topical Skin Adhesive is intended for topical applications only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, simple, thoroughly cleansed, trauma induced lacerations.**

SurgiSeal ™Topical Skin Adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K082993