K101276

CHEMENCE MEDICAL PRODUCTS

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Section 5. Abbreviated 510(k) Summary

Submitted By:

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JUL 2 8 2010

Contact Person:

Patricia D. Lehman
Director of Regulatory Affairs
Phone: 678-879-5446 Ext. 201
Email: plehman@chemence-us.com

Date of Summary: April 30, 2010

Device Trade Name: derma+flex QS High Viscosity Tissue Adhesive

Common Name: Topical Skin Adhesive

Classification Name: Tissue Adhesive (21CFR 878.4010)
Product Code: MPN

Predicate Device: High Viscosity Dermabond Topical Skin Adhesive

Device Description: ***derma+flex*® QS™** High Viscosity Tissue Adhesive is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. It is provided in a single use aluminum collapsible tube packaged in a RXM 48gaPET-200LDPE Film/1059B uncoated Tyvek pouch also containing 2 Indothene HD Grade HD50MA180 applicator tips. The dauber applicator is comprised of a self-puncturing cap and a foam surface, which allows spreading of the adhesive with uniformity. The nozzle applicator is also a self-puncturing cap with an elongation that enables detailed application of the adhesive. As applied to skin, the liquid is syrup-like in viscosity and polymerizes within minutes. ***derma+flex*® QS™** High Viscosity Tissue Adhesive has a syrup-like viscosity. The increased viscosity ***derma+flex*® QS™** is intended to reduce the risk of unintended placement of the adhesive during application due to migration of the liquid adhesive from the wound site.

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Indications for Use:

***derma+flex*® QS™** High Viscosity Tissue Adhesive is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including punctures from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. ***derma+flex*® QS™** High Viscosity Tissue Adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

Substantial Equivalence:

***derma+flex*® QS™** High Viscosity Tissue Adhesive is substantially equivalent to High Viscosity Dermabond Topical Skin Adhesive with regard to Indication for Use, formulation, technology, target population, intended application, mechanism of action and performance at achieving their intended use. Both devices present the same main chemical characteristics (2-Octyl Cyanoacrylate) and equivalent formulating materials with similar chemical characteristics. Devices shown to be equivalent in all performance and safety tests.
***derma+flex*® QS™** High Viscosity Tissue Adhesive was evaluated in tests to establish a performance and safety profile in accordance with the *Class II Specials Controls Guidance Document: Tissue Adhesive for Topical Approximation of Skin.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 2 8 2010

Chemence Medical Products, Inc.
% Ms. Patricia D. Lehman
Director of Regulatory Affairs
185 Bluegrass Valley Parkway, Suite 100
Alpharetta, Georgia 30005-2222

Re: K101276
Trade/Device Name: derma+flex® QS™ High Viscosity Tissue Adhesive
Regulation Number: 21 CFR 878.4010(a)
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: May 04, 2010
Received: May 06, 2010

Dear Ms. Lehman:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101276

Indications for Use

JUL 28 2010

510(k) Number:

Device Name: *derma+flex*® QS™ High Viscosity Tissue Adhesive

Indications for Use:

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***derma+flex*® QS™** High Viscosity Tissue 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K101276