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K050757

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510(k) SUMMARY
DERMA+FLEX™ Gel Adhesive

Submitted by:	Chemence Medical Products, Inc. 185 Bluegrass Valley Parkway Alpharetta, GA 30005 Telephone: 770.664.6624 FAX: 770.664.6620
Contact name:	Scott Leal, Regulatory Affairs/Quality Assurance
Date prepared:	January 13, 2006
Device trade name(s):	DERMA+FLEX™ Gel Adhesive:
Common name:	Liquid Bandage
Classification regulation no.:	880.5090
Classification:	Class I
Predicate devices:	Liquiderm™ Liquid Adhesive Bandage, which is manufactured by Closure Medical Corp., **K002338**, (*Marketed as Johnson & Johnson Band-Aid® Liquid Bandage*). 3M ™ Liquid Bandage, which is manufactured by 3M Health Care, **K031263**, (*Marketed as 3M NEXCARE™ Liquid Bandage*). LiquiShield™ Liquid Bandage, which is manufactured by MedLogic Global Limited, **K031321**.
Contraindications:	Care should be used around the eyes. Do not use on skin with active signs of infection. Avoid placing adhesive into major wounds or indications that should otherwise require wounds closure with another device.
Description:	DERMA+FLEX™ Gel Adhesive is a sterile, clear, high viscosity, flexible, liquid topical bandage composed of a blend of 2-Octyl and N-Butyl cyanoacrylate monomers with an octyl cyanoacrylate polymer, tributyl citrate (a plasticizer) and containing D&C violet #2 pigment. DERMA+FLEX™ is supplied in 0.5g single patient use aluminum tubes with (2) self-piercing applicator caps (a dauber cap and a nozzle cap). Each sterile single use

aluminum tube is packaged with applicators in individual Tyvek pouches and sterilized by EtO sterilization rendering the exterior of the tube and applicators suitable for dispensing on sterile fields.

Indications for Use: DERMA+FLEX™ Gel Adhesive is indicated for OTC use to cover minor cuts, scrapes and minor irritations of the skin and help protect them from infection.

Technological Characteristics: DERMA+FLEX™ Gel Adhesive is applied to the wound and polymerizes to form a mechanical bond with the skin, typically within one to 5 minutes depending on thickness applied. Once polymerized, the topical film acts as a covering allowing the wound to heal. During wound healing, the polymer coating sloughs off naturally, as dead skin cells are shed and replaced with new cells.

Substantial Equivalence: DERMA+FLEX™ Gel Adhesive is similar to the predicate devices (Liquiderm™ Liquid Adhesive Bandage, 3M™ Liquid Bandage and LiquiShield™ Liquid Bandage) in that all are cyanoacrylate liquid bandages, manufactured in a similar manner (synthesized, cracked, and distilled), blended with other ingredients and sterilized by dry heat. The products are substantially equivalent.

Differences: The DERMA+FLEX™ Gel Adhesive formulation incorporates a 99.0% pure octyl cyanoacrylate polymer as an ingredient to increase the viscosity of the gel to help control the gel's application until it polymerizes. Once the Gel Adhesive polymerizes, the octyl polymer become part of the polymer matrix and is indistinguishable from the polymerized monomers.

The sterilized DERMA+FLEX™ tubes are packaged with applicators in individual Tyvek pouches and sterilized by EtO sterilization rendering the exterior of the tube and applicators suitable for dispensing on sterile fields.

Testing Summary: An In-Vitro Cytotoxicity L929 Agar Overlay Test was completed on Derma+Flex™ Gel Adhesive to determine the cytotoxicity of the product. The test result was a reactivity grade from 0 to 1. In this test the Derma+Flex™ Gel Adhesive met the requirements of the cytotoxicity test as detailed in ISO 10993-5 and USP 24, Biological Reactive Tests In-Vitro (87). The product was considered safe for its use.

A Murine Local Lymph Node Assay (LLNA) was completed to evaluate Derma+Flex™ Gel Adhesive for irritation and sensitivity. The material was not considered to be sensitizing.

An Intracutaneous Inject Test was completed on Derma+Flex™ Gel Adhesive to screen extracts for potential irritation effects as a result of an intracutaneous injection. The saline yielded a mean score of 0.0 and the cottonseed oil a mean score of 1.4 out of a possible 4. Based on this test, the article is considered a mild irritant. The following warning label is provided on the package, consistent with the predicated devices: "Do not use this product if you are allergic to cyanoacrylate".

Derma+Flex™ Gel Adhesive has also been subjected to mechanical and performance testing to demonstrate equivalence to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 3 2006

Mr. Scott Leal
Official Correspondent
Chemence Medical Products, Inc.
185 Bluegrass Valley Parkway, Suite 100
Alpharetta, Georgia 30005

Re: K050757
Trade/Device Name: DERMA+FLEX™ Gel Adhesive
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: January 13, 2006
Received: January 17, 2006

Dear Mr. Leal:

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.

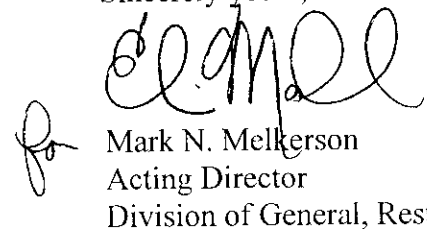
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Acting 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): K050757

Device Name: DERMAFLEX™ Gel Adhesive

Indications for Use: DERMA+FLEX™ Gel Adhesive is indicated for use to cover minor cuts, scrapes and minor irritations of the skin and help protect them from infection.

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

Division Sign-Off 8/9/05

Division of General, Restorative, and Neurological Devices

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