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Appendix 2

510(k) Summary

Submitted by:	MedLogic Global Limited, Western Wood Way, Langage Science Park, Plymouth, Devon, PL7 5BG, England Telephone: 44 1752 209955 Fax: 44 1752 209956
Contact name:	Richard Stenton, Managing Director
Date prepared:	23rd October 2003
Device trade name:	LiquiShield™ Liquid Bandage
Common name:	Liquid Bandage
Classification name:	Liquid Bandage
Classification regulation no.:	880.5090
Classification:	Class 1
Predicate device:	LIQUIDERM™ Liquid Adhesive Bandage manufactured by Closure Medical Corp., K002338, (Marketed as Johnson & Johnson Band-Aid® Liquid Bandage).
Intended use:	LiquiShield™ Liquid Bandage is intended for over the counter (OTC) use to cover minor cuts and scrapes and minor irritations of the skin and help protect them from infection.
Contraindications:	Application to: Burns or wounds with active signs of infection Deep puncture wounds Animal bites Serious burns

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Description:

LiquiShield™ Liquid Bandage biocompatible cyanoacrylate-based, drying, liquid barrier film for the protection the skin. It is applied as a liquid and dries, within approximately 45 seconds, adhering to the contours of the skin to form a transparent, flexible film. LiquiShield™ Liquid Bandage wears off naturally as the skin regenerates. The applicator and contents are supplied sterile, and the device is, therefore, suitable for aseptic techniques.

Substantial equivalence:

LiquiShield™ Liquid Bandage is substantially equivalent to the following predicate device:

LIQUIDERM™ Liquid Adhesive Bandage manufactured by Closure Medical Corp., K002338, (Marketed as Johnson & Johnson Band-Aid® Liquid Bandage).

LiquiShield™ Liquid Bandage is applied as a liquid, which, upon contact with the skin, dries to form a barrier film, which is substantially equivalent to the predicate device. Substantial equivalence is also based on intended use, application, product performance, haemostatic, quick drying, keeps out dirt and germs, waterproof and flexibility properties.

Testing summary:

LiquiShield™ Liquid Bandage has been subjected to the appropriate biocompatibility testing in accordance with BSENISO 10993-1, the results of which confirm that the product is safe for its intended use. LiquiShield™ Liquid Bandage has also been subjected to mechanical and performance testing to demonstrate equivalence to the predicate device, with clinical evaluations conducted to demonstrate that LiquiShield™ Liquid Bandage meets its intended use requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 1 2004

Mr. Mel Longhurst
MedLogic Global Limited
Western Wood Way
Langage Science Park
Plymouth, Devon, PL7 5BG
England

Re: K031321
Trade/Device Name: Liquishield Liquid Bandage
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: I
Product Code: KMF
Dated: November 7, 2003
Received: November 12, 2003

Dear Mr. Longhurst:

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

Indications for Use

510(k) Number (if known): K031321

Device Name: LIQUISHIELD LIQUID BANDAGE

Indications For Use:

LiquiShield™ Liquid Bandage is intended to cover minor cuts and scrapes and minor irritations of the skin and help protect them from infection.

Prescription Use _____ AND/OR Over-The-Counter Use OTC 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 of General, Restorative and Neurological Devices

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