K023163

510 (k) Notification – LiquiShield®-S

510(k) Summary

JAN 13 2003

Submitted by:	MedLogic Global Limited Western Wood Way Langage Science Park Plymouth, Devon. PL7 5BG UK +44 1752 209955
Contact Name:	Howard Beaumont
Date prepared:	13th September 2002
Device Trade Name:	LiquiShield®-S
Common Name:	Liquid Barrier Film
Classification name:	Liquid Bandage: CFR 880.5090
Classification	Class 1
Predicate Device:	3M No Sting Barrier Film 3M Medical Products Group K955103

Intended Use:

LiquiShield™-S is intended to protect intact or damaged skin from the effects of moisture, friction, (rubbing) or shear (tearing).

LiquiShield™-S helps protect skin exposed to irritation from moisture such as urine, faeces, digestive juices and wound drainage.
LiquiShield™-S can also be used in areas that are exposed to friction and shear such as occurs when items, such as bedding, clothing, or shoes, rub against the skin.

LiquiShield™-S helps protect the skin against irritation caused by adhesive products.

Contraindications:

Do not apply directly to deep, open, or bleeding wounds.
Do not apply to chronic wounds
Do apply to second or third degree burns.
Do not apply to infected areas

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Description:

LiquiShield®-S is a non-cytotoxic (not harmful to the body) cyanoacrylate based, rapid drying, liquid barrier film for the protection of the skin. It is applied as a liquid and dries, within 45 seconds, adhering to the contours of the skin to form a transparent flexible film. LiquiShield®-S will wear off, naturally, as the skin regenerates. The applicator and packaging are sterilized.

Substantial Equivalence:

LiquiShield®-S Liquid Barrier film is substantially equivalent to the following predicate device:

No Sting Barrier Film – 3M™ Medical Products Group K955103

LiquiShield®-S is applied as a liquid solution, 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 upon intended use, application, product performance, including MVTR rates, waterproof properties, friction reduction and barrier film duration.

Testing Summary:

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2003

Mr. Howard Beaumont
Director of Quality Assurance
and Regulatory Affairs
MedLogic Global Limited
Western Wood Way
Langage Science Park
Plympton, Plymouth
Devon PL7 5BG
England

Re: K023163
Trade/Device Name: LiquiShield® -S
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid Bandage
Regulatory Class: I
Product Code: KMF
Dated: December 23, 2002
Received: December 26, 2002

Dear Mr. Beaumont:

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. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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

K023163

510 (k) Notification – LiquiShield®-S

Applicant: MedLogic Global Limited

510(k) Number (if known): _____

Device Name: LiquiShield®-S

Indications for Use:

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LiquiShield®-S can also be used in areas that are exposed to friction and shear such as occurs when items, such as bedding, clothing, or shoes, rub against the skin.

LiquiShield®-S helps protect the skin against irritation caused by adhesive products.

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

510(k) Number K023163

Prescription Use _____ OR Over-The-Counter Use _____
(per 21 CFR 801.109)

(Optional Format 1-2-96)