

K083531

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## 5.0 TRADITIONAL 510(K) SUMMARY

**Submitted by:** MedLogic Global, Ltd.  
Western Wood Way  
Langage Science Park  
Plymouth, Devon, UK PL 5 BG

**CONTACT PERSON:** Tierney Norsted Ph.D., M.P.H.  
Exec Vice President, Sr. Principal Advisor  
Regulatory & Clinical Research Institute, Inc.  
5353 Wayzata Blvd., Suite 505  
Minneapolis, Minnesota 55416  
952-746-8021  
tnorsted@rcri-inc.com

**Date of Summary:** February 11, 2009

**Device Trade Name:** LiquiBand® Topical Skin Adhesive

**Product Code:** LB 0004

**Common or Usual Name:** Topical Skin Adhesive

**Classification Name:** Tissue Adhesive (21 CFR 878.4010)

**Predicate Device(s):** Indermil® Tissue Adhesive (P010002)

**Device Description:** LiquiBand Topical Skin Adhesive is a sterile, topical tissue adhesive containing n-butyl-2-cyanoacrylate. LiquiBand Topical Skin Adhesive is supplied in a single patient use 0.5g High Density Polyethylene ampoule with polypropylene applicator tip.

**Indication for Use:** LiquiBand Topical Skin Adhesive is indicated for the closure of topical skin incisions including laparoscopic incisions, and trauma-induced lacerations in areas of low skin tension that are simple, thoroughly cleansed, and have easily approximated edges. LiquiBand Topical Skin Adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

**Substantial Equivalence:** LiquiBand Topical Skin Adhesive is substantially equivalent to Indermil Tissue Adhesive (P010002) with regard to Indication For Use, formulation, technology, target population, intended application, mechanism of action and performance at achieving their intended use.

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**Substantial Equivalence  
Testing Summary:**

The following comparative testing demonstrated substantially equivalent performance between LiquiBand Topical Skin Adhesive and Indermil Tissue Adhesive:

- Tensile strength (ASTM F2255-05, F2258-05, F2458-05)
- Set (polymerization) time
- Heat of polymerization
- Viscosity
- Hydrolytic degradation
- Applicator expression force
- Water vapor transmission rate
- GC Chemical Analysis



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 12 2009

MedLogic Global Ltd.  
% Tierney Norsted, Ph.D., M.P.H.  
Regulatory & Clinical Research Institute, Inc.  
5353 Wayzata Blvd.  
Minneapolis, MN 55416

Re: K083531

Trade/Device Name: LiquiBand Tissue Adhesive  
Regulation Number: 21 CFR 878.4010 (a)  
Regulation Name: Tissue adhesive for topical approximation of skin  
Regulatory Class: II  
Product Code: MPN  
Dated: November 26, 2008  
Received: November 28, 2008

Dear Dr. Norsted:

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  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

#### 4.0 INDICATIONS FOR USE STATEMENT

510(k) Number: K083531

Device Name: LiquiBand® Topical Skin Adhesive

Model Number: LB 0004

**Indications For Use:** LiquiBand® Topical Skin Adhesive is indicated for the closure of topical skin incisions including laparoscopic incisions, and trauma-induced lacerations in areas of low skin tension that are simple, thoroughly cleansed, and have easily approximated edges. LiquiBand Topical Skin Adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

Prescription Use: **YES**  
(Part 21 CFR 801 Subpart D)

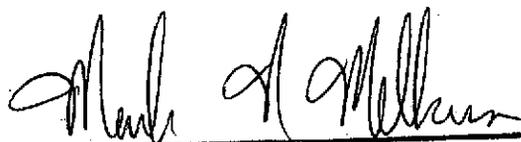
AND/OR

Over-the-Counter Use: **NO**  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



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

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