

**5.0 TRADITIONAL 510(K) SUMMARY**

APR - 9 2010

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

**Contact Person:** Michael Browne  
Quality and Regulatory Affairs Manager  
MedLogic Global, Ltd

**Date of Summary:** 17<sup>th</sup> March 2010

**Device Trade Name:** LiquiBand® Ultima

**Product Code:** LUT 003

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

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

**Predicate Device(s):** LiquiBand® LB 0004 (K083531)

**Device Description:** LiquiBand® Ultima is a sterile, topical tissue adhesive containing n-butyl-2-cyanoacrylate. LiquiBand® Ultima is supplied in a single patient use dual tip configuration.

**Indication for Use:** LiquiBand® Ultima 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® Ultima may be used in conjunction with, but not in place of, deep dermal stitches.

**Substantial Equivalence:** LiquiBand® Ultima is substantially equivalent to LiquiBand Topical Skin Adhesive (K083531) with regard to Indication For Use, formulation, technology, target population, intended application, mechanism of action and performance at achieving their intended use.

**Substantial Equivalence  
Testing Summary:**

The following comparative testing demonstrated substantially equivalent performance between LiquiBand Ultima and LiquiBand:

- Tensile strength (ASTM F2255-05, F2258-05, F2458-05)
- Set (polymerization) time
- Heat of polymerization
- Viscosity
- GC Chemical Analysis



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-066-0609  
Silver Spring, MD 20993-0002

APR - 9 2010

MedLogic Global, Ltd.  
% Mr. Michael Browne  
Quality and Regulatory Affairs Manager  
Western Wood Way – Langage Science Park  
Plymouth, Devon, PL7 5BG, United Kingdom

Re: K100284

Trade/Device Name: LiquiBand® Ultima  
Regulation Number: 21 CFR 878.4010  
Regulation Name: Tissue adhesive  
Regulatory Class: Class II  
Product Code: MPN  
Dated: March 17, 2010  
Received: March 22, 2010

Dear Mr. Browne:

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

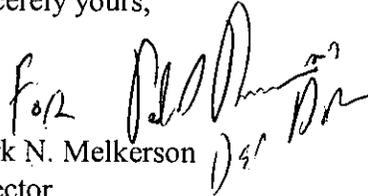
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CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and 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/ucml15809.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,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a date '10/2' written to the left.

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

Enclosure

## 4.0 INDICATIONS FOR USE STATEMENT

510(k) Number: K100284

Device Name: LiquiBand® Ultima

Model Number: LUT 003

**Indications For Use:** LiquiBand Ultima topical skin adhesive is intended for topical applications 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. LiquiBand Ultima topical skin adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

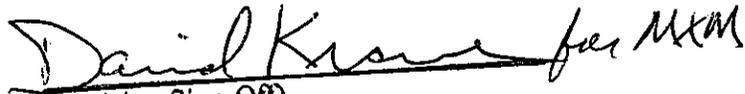
Prescription Use: **YES**  
(Part 21 CFR 801 Subpart D)

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K100284