



Food and Drug Administration  
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October 26, 2015

Advanced Medical Solutions (Plymouth) Ltd.  
Dr. Martin Mitchell  
Western Wood Way  
Language Science Park  
Plymouth, Devon. PL7 BG  
United Kingdom

Re: K151182  
Trade/Device Name: LiquiBand Exceed  
Regulation Number: 21 CFR 878.4010  
Regulation Name: Tissue Adhesive  
Regulatory Class: Class II  
Product Code: MPN  
Dated: September 23, 2015  
Received: September 28, 2015

Dear Dr. Mitchell:

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

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

**David Krause -S**

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K151182

Device Name  
LiquiBand Exceed

### Indications for Use (Describe)

LiquiBand Exceed 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 Exceed topical skin adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) Summary**  
**(In accordance with 21 CFR 807.92)**

**Advanced Medical Solutions (Plymouth) Ltd**  
**LiquiBand Exceed**

**1. Submitter**

Submitted by: Advanced Medical Solutions (Plymouth) Ltd.  
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Contact Person: Dr Martin Mitchell  
Regulatory Affairs Associate  
Advanced Medical Solutions (Plymouth) Ltd

Date of Summary: October 2015

**2. Device**

Device Name: LiquiBand Exceed  
Common or Usual Name: Topical Skin Adhesive  
Classification Name: Tissue Adhesive (21 CFR 878.4010)  
Regulatory Class: Class II  
Product Code: MPN

**3. Predicate Device**

Device Name: Barle Tissue Adhesive 2  
510(k) Clearance: K132243

**4. Device Description**

LiquiBand Exceed topical skin adhesive is a sterile, liquid topical skin adhesive containing a monomeric (2-Octyl-cyanoacrylate) formulation and the colorant D&C Violet #2. It is provided in a single patient use applicator and packaged in a pouch. The LiquiBand Exceed topical skin adhesive product is comprised of a crushable glass ampoule contained within a plastic applicator with attached foam applicator tip.

LiquiBand Exceed topical skin adhesive remains liquid until it is applied to the skin. Upon application LiquiBand Exceed topical skin adhesive polymerizes within minutes.





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In vitro studies have shown that LiquiBand Exceed topical skin adhesive acts as a barrier to microbial penetration as long as the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties and a correlation between microbial barrier properties and a reduction in infection have not been established.

A single device contains sufficient adhesive to close wound(s) up to a combined length of 30cm.

LiquiBand Exceed topical skin adhesive is suitable for intraoperative reuse, for up to 90 minutes on a single patient.

## 5. Indications for Use

LiquiBand Exceed 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 Exceed topical skin adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

## 6. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of LiquiBand Exceed and the predicate device are similar, in that they both contain the same high level elements.

- A cyanoacrylate based tissue adhesive
- An ampoule to house the adhesive
- An applicator device to apply the adhesive

The following technological differences exist between LiquiBand Exceed and the predicate device.

- Applicator design
- Volume of adhesive

LiquiBand Exceed also has the following additional claims

- A single device contains sufficient adhesive to close wound(s) up to a combined length of 30cm.
- LiquiBand Exceed topical skin adhesive is suitable for intraoperative reuse, for up to 90 minutes on a single patient.

## 7. Performance Data

Testing was performed in accordance with the FDA special controls guidance document for "Tissue Adhesive for the Topical Approximation of Skin"

### Sterilization and Shelf Life

LiquiBand Exceed is sterilized by dry heat and ethylene oxide gas. The shelf life of the device has been confirmed through both real time and accelerated aging studies.





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#### Performance Testing

The following tests were performed on the LiquiBand Exceed device to demonstrate substantial equivalence to the predicate device and to substantiate the new claims:

- Wound closure strength (ASTM F2458-05)
- Lap-shear strength (ASTM F2255-05)
- Peel adhesion strength (ASTM F2256-05)
- Adhesive strength in tension (ASTM F2258-05)
- Force to actuate
- Polymerization set time
- Microbial barrier
- Intraoperative reuse
- Wound closure length

The following tests were performed on the predicate device and were referenced in support of LiquiBand Exceed:

- Degradation rate
- Heat of polymerization
- Viscosity
- Purity
- Moisture determination

#### Biocompatibility

The biological evaluation of the LiquiBand Exceed device was performed in accordance with ISO 10993-1 "Biological evaluation of medical devices. Evaluation and testing". The following test reports were provided in this submission:

- Cytotoxicity
- Sensitization
- Irritation
- Acute dermal toxicity
- Intramuscular implantation

### **8. Conclusions**

Extensive design verification, functional and performance testing have been conducted. Based on the testing carried out, LiquiBand Exceed has been demonstrated to be substantially equivalent to the predicate device, Barle Tissue Adhesive 2 (K132243).

