March 9, 2020

Advanced Medical Solutions Limited
Martin Mitchell
Senior Regulatory Affairs Associate
Western Wood Way , Langage Science Park
Plymouth, PL7 5BG Gb

Re: K183570
Trade/Device Name: LiquiBand Plus
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue Adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: March 9, 2020
Received: March 9, 2020

Dear Martin 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183570

Device Name
LiquiBand Plus

Indications for Use *(Describe)*
LiquiBand® Plus 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® Plus 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

Submitted by:	Advanced Medical Solutions Limited Western Wood Way Langage Science Park Plymouth, Devon. PL7 5BG United Kingdom Tel: +44 (0)1752 209955 Fax: +44 (0) 1752 209956
Contact Person:	Martin Mitchell Senior Regulatory Affairs Associate
Date of Summary:	5th March 2020
Device Name:	LiquiBand® Plus
Common Name:	Topical Skin Adhesive
Classification Name:	Tissue adhesive
Regulatory Number:	21 CFR 878.4010
Device Class:	Class II
Product Code:	MPN
Predicate Device	
Device Name:	LiquiBand® Exceed
510(k) Clearance:	K151182
Reference Device	
Device Name:	High Viscosity Dermabond® Mini Topical Skin Adhesive
510(k) Clearance:	K152096

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Device Description

LiquiBand® Plus 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® Plus topical skin adhesive product is comprised of a crushable glass ampoule contained within a plastic applicator with attached foam applicator tip. LiquiBand® Plus topical skin adhesive remains liquid until it is applied to the skin. Upon application LiquiBand® Plus topical skin adhesive polymerizes within minutes.

In vitro studies have shown that LiquiBand® Plus 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.

Indications for Use

LiquiBand® Plus 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® Plus may be used in conjunction with, but not in place of, deep dermal stitches.

Comparison of Technological Characteristics with the Predicate Device

A comparison of the technological characteristics of LiquiBand® Plus and the predicate device are outlined below:

- **Applicator tip:** LiquiBand® Plus has a polyethylene tip base and foam. The predicate has a polypropylene tip base and a polyurethane foam.
- **Adhesive accelerant:** LiquiBand® Plus contains an accelerant in the foam tip.
- **Applicator body:** The LiquiBand® Plus applicator has the same design but is 10mm shorter in length compared to the predicate.
- **Adhesive:** Both devices contain a 2-octyl cyanoacrylate based adhesive with D&C Violet #2 colorant. LiquiBand® Plus contains 0.41g and the predicate contains 0.80g of adhesive.

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Performance Data

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

Performance Testing

The following tests were performed on LiquiBand® Plus to demonstrate substantial equivalence to the predicate device:

- Lap-shear strength (ASTM F2255-05)
- T-peel adhesion strength (ASTM F2256-05)
- Adhesive strength in tension (ASTM F2258-05)
- Wound closure strength (ASTM F2458-05)
- Degradation rate
- Accelerant degradation assessment
- Heat of polymerisation
- Force to actuate and express
- Viscosity
- Polymerization set time and clog time
- Microbial barrier testing
- Quality of film testing
- Animal wound healing study

Biocompatibility

The biological evaluation of LiquiBand® Plus was performed in accordance with FDA guidance on the use of ISO 10993-1. The following endpoints were addressed as part of the submission:

- Cytotoxicity
- Sensitization
- Irritation
- Acute systemic toxicity
- Implantation
- Subacute systemic toxicity
- Material-mediated pyrogenicity

Conclusions

Based on the intended use, technological characteristics, safety and performance testing, LiquiBand® Plus has been demonstrated to be substantially equivalent to the predicate device, LiquiBand® Exceed.