May 23, 2022

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

Re: K211878
Trade/Device Name: LiquiBand® XL
Regulation Number: 21 CFR 878.4011
Regulation Name: Tissue Adhesive With Adjunct Wound Closure Device For Topical Approximation Of Skin
Regulatory Class: Class II
Product Code: OMD
Dated: May 4, 2022
Received: May 4, 2022

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,

Julie Morabito, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211878

Device Name
LiquiBand® XL

Indications for Use *(Describe)*
LiquiBand® XL is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. LiquiBand® XL should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

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.

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510(k) Summary

Submitted by:
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Contact Person:
Martin Mitchell
Regulatory Affairs Manager

Date of Summary:
19th May 2022

Device Name:
LiquiBand® XL

Common Name:
Cutaneous Tissue Adhesive With Mesh

Classification Name:
Tissue adhesive with adjunct wound closure device for topical approximation of skin

Regulatory Number:
21 CFR 878.4011

Device Class:
Class II

Product Code:
OMD

Predicate Device
Device Name: Exofin Fusion Skin Closure System
510(k) Clearance: K191461

Reference Device
Device Name: LiquiBand® Plus
510(k) Clearance: K183570

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Device Description

LiquiBand® XL is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet No. 2. It is provided in a single-use applicator. As applied to skin, the liquid topical skin adhesive is slightly more viscous than water and polymerizes within minutes.

In vitro studies have shown that LiquiBand® XL 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.

LiquiBand® XL also incorporates a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment to an incision until the liquid adhesive is applied to achieve skin closure.

Indications for Use

LiquiBand® XL is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple, thoroughly cleansed, trauma-induced lacerations. LiquiBand® XL should be used in conjunction with, but not in place of, deep dermal stitches. Additionally, the adjunct wound closure device component maintains temporary skin edge alignment along the length of the wound during application of the liquid adhesive.

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the LiquiBand® XL and the predicate device are similar, in that they both contain the same technological characteristics:

Device	Subject device: LiquiBand® XL	Predicate device: Exofin Fusion Skin Closure System	Comparison
Adhesive	2-octyl cyanoacrylate adhesive with D&C Violet #2 colorant	2-octyl cyanoacrylate adhesive with D&C Violet #2 colorant	Same
Accelerant	Quaternary ammonium salt	Quaternary ammonium salt	Same
Applicator	Sterile single use applicator; comprising of a glass ampoule (containing the adhesive) within a plastic applicator body with a porous block (containing the accelerant) with a foam applicator tip	Sterile single use applicator; comprised of an aluminum tube (containing the adhesive) with a porous disk (containing the accelerant) with an applicator tip	Equivalent
Mesh	Polyester mesh with pressure sensitive adhesive	Polyester mesh with pressure sensitive adhesive	Same

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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 the LiquiBand® XL to demonstrate substantial equivalence to the predicate device:

- Peel Adhesion of Pressure-Sensitive Tape (ASTM D3330/D3330M-04)
- Shear Adhesion of Pressure-Sensitive Tapes (ASTM D3654/D3654M-06)
- Tensile Properties of Thin Plastic Sheeting (ASTM D882-12)
- 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)
- Adhesive degradation study
- Heat of polymerization
- Force to actuate and express
- Viscosity
- Polymerization set time
- Microbial barrier testing
- Quality of adhesive film on mesh
- Accelerant degradation study
- Animal wound healing study

Biocompatibility

The biological evaluation of the LiquiBand® XL was performed in accordance with FDA guidance on the use of ISO 10993-1. The following test reports were provided in this submission:

- Cytotoxicity
- Sensitization
- Irritation
- Material mediated pyrogenicity
- Acute systemic toxicity
- Chemical characterization and toxicological risk assessment

Clinical Testing

- No clinical testing has been submitted, referenced, or relied upon for determining substantial equivalence.

Conclusions

Based on the intended use, technological characteristics, safety and performance testing, LiquiBand® XL has been demonstrated to be substantially equivalent to the predicate device, Exofin Fusion Skin Closure System.