June 5, 2020

Chemence Medical, Inc.
Kenneth Broadley
Executive Vice President
200 Technology Drive
Alpharetta, Georgia 30005

Re: K191461
Trade/Device Name: Exofin Fusion Skin Closure System
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, 2020
Received: May 6, 2020

Dear Kenneth Broadley:

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,

Anjana Jain, Ph.D.
Acting 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191461

Device Name
Exofin Fusion Skin Closure System

Indications for Use *(Describe)*
Exofin Fusion Skin Closure System 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. Exofin Fusion Skin Closure System 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.**

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

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# 510(k) Summary

**Submitted By:** Chemence Medical, Inc.
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**Contact Person:** Dr. Kenneth N. Broadley
Chief Regulatory and Quality Officer
Phone: 678-689-0761
Email: kbroadley@chemence.com

**Date of Summary:** June 5, 2020

**Trade Name:** Exofin® Fusion Skin Closure System

**Common Name:** Topical Adhesive with Mesh

**Classification Name:** Tissue Adhesive with Adjunct Wound Closure Device for Topical Approximation of Skin (21 CFR 878.4011)

**Regulatory Class:** Class II

**Product Code:** OMD

**Device Description:** Exofin® Fusion Skin Closure System 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-use applicator packaged in a rigid blister. As applied to skin, the liquid is slightly more viscous than water and polymerizes within minutes. In vitro studies have shown that Exofin® Fusion Skin Closure System 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. Exofin Fusion Skin Closure System also incorporates a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment of incisions up to 20 cm each in length until the liquid adhesive is applied to achieve skin closure.

**Intended Use:** Exofin® Fusion Skin Closure System is intended for topical application 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. exofin®

Fusion Skin Closure System 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.

**Predicate Devices:** K171442 Exofin® Fusion Skin Closure System

**Reference Device:** K152476 Exofin® High Viscosity Tissue Adhesive

**Comparison of Technological Characteristics with the Predicate Devices:**

Exofin® Fusion® Skin Closure System is the same as the predicate device with regard to intended use, mechanism of action and performance characteristics. Both devices contain a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment of wounds of up to 20 cm in length until a liquid topical adhesive is applied to achieve wound closure. The liquid adhesive formulations, the mesh materials, and the method of adhesive application are all the same.

The predicate included two mesh strips of 22 cm in length by 4 cm in width, accompanied by 4 gm of liquid adhesive housed in an aluminum tube, while the subject device is provided with a single 22 X 4 cm mesh and 2 x 1.75 gm of adhesive in the aluminum tubes.

Both the subject device and the predicate device utilize a chemical that initiates the polymerization (curing) of the adhesive as it is applied. However, in the subject device the chemical is impregnated into the porous disk within the applicator assembly, instead of being coated on the mesh as in the predicate. Additionally, the impregnated porous disk of the subject Exofin Fusion Skin Closure system also includes a chemical that accelerates the polymerization of the adhesive; this chemical is not present in the predicate device.

**Comparison Table:**

| Attribute | Subject device | Predicate | Comparison |
|---|---|---|---|
| Trade Name | Exofin Fusion Skin Closure System | Exofin Fusion Skin Closure System | Same |
| 510(k) No. | K191461 | K171442 | NA |
| Common Name | Cutaneous Tissue Adhesive with Mesh | Cutaneous Tissue Adhesive with Mesh | Same |
| Product Code | OMD | OMD | Same |
| Regulation | 21 CFR 878.4011 | 21 CFR 878.4011 | Same |

| Attribute | Subject device | Predicate Device | Comparison |
|---|---|---|---|
| Indications | Exofin Fusion® Skin Closure System is intended for topical application only to hold easily closed approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple thoroughly cleansed, trauma-induced lacerations.<br>Exofin Fusion® Skin Closure Systemshould 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. | Exofin Fusion® Skin Closure Systemis intended for topical application only to hold easily closed approximated skin edges of wounds from surgical incisions, including incisions from minimally invasive surgery, and simple thoroughly cleansed, trauma-induced lacerations.<br>Exofin Fusion® Skin Closure System 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. | Same |
| Adhesive Formulation | 2-octylcyanoacrylate based formulation | 2-octylcyanoacrylate based formulation | Same |
| Mesh | Polyester with acrylic pressure sensitive adhesive | Polyester with acrylic pressure sensitive adhesive | Same |
| Activator | Quaternary ammonium salt in applicator | Quaternary ammonium salt on mesh | Equivalent |
| Accelerant | Crown ether in applicator | Crown ether on mesh | Equivalent |
| Product Sterilization | Heat and ethylene oxide | Heat and ethylene oxide | Same |

**Non-clinical Testing**: Testing was performed in accordance with the FDA Class II Special Controls Guidance Document: Tissue Adhesive with Adjunct Wound Closure Device Intended for the Topical Approximation of Skin. The following tests were performed on Exofin® Fusion Skin Closure System to demonstrate substantial equivalence:

- Wound closure strength (ASTM F2458-05)
- Adhesive strength in tension (ASTM F2258-05)
- T-peel adhesion strength (ASTM F2256-05)
- Lap-shear strength (ASTM F2255-05)
- Heat of polymerization
- Microbial barrier effectiveness
- Extractables and Leachables

**Biocompatibility Testing:** Biocompatibility testing was conducted according to the requirements of FDA Guidance Document Use of International Standard ISO 10993-1 "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process" for a surface device in prolonged contact with a breached or compromised surface.

**Clinical Testing:** No clinical testing has been submitted, referenced, or relied upon for determining substantial equivalence.

**Conclusion:** Based on the intended use, technological characteristics, and performance testing, the subject Exofin® Fusion Skin Closure System has been shown to be substantially equivalent to the predicate.