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December 17, 2020

Chemence Medical, Inc.
Charnelle Thomas
Director of Regulatory Affairs
200 Technology Drive
Alpharetta, Georgia 30005

Re: K200264
Trade/Device Name: Exofin® High Viscosity Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue Adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: November 16, 2020
Received: November 17, 2020

Dear Charnelle Thomas:

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,

For Kimberly 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)*
K200264

Device Name
Exofin® High Viscosity Topical Skin Adhesive

Indications for Use *(Describe)*
Exofin® High Viscosity Topical Skin Adhesive 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® High Viscosity Topical Skin Adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

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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Traditional 510(k) for Exofin® High Viscosity Topical Skin Adhesive

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510(k) Summary

This 510(k) summary is prepared in accordance with 21 CFR 807.92.

1. Submitter

Submitted by: Chemence Medical, Inc.
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Alpharetta, GA 30005-3926
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Fax: 678-820-3320

Contact Person: Charnelle Thomas
Director, Regulatory Affairs
Chemence Medical, Inc.
Phone: 678-690-0760
Email: cthomas@chemence.com

Date of Summary: December 14, 2020

2. Device

Device Proprietary Name: Exofin® High Viscosity Topical Skin Adhesive

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

Legally marketed devices to which equivalence is claimed:

Device Name: Exofin® High Viscosity Tissue Adhesive

510(k) Clearance: K152476

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Traditional 510(k) for Exofin® High Viscosity Topical Skin Adhesive

4. Device Description

Exofin® High Viscosity Topical Skin Adhesive is a sterile liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation for rapid polymerization, and the colorant D&C Violet #2 which aids in visualization during application. It is provided in a single-use, aluminum, collapsible tube fitted with a polyethylene-based applicator tip. The applicator tip consists of three components, a connector fitted with a self-puncturing cap, porous disk and soft elastomeric brush, used to apply and spread the adhesive evenly. The adhesive and applicator tip are packaged together in a polyethylene terephthalate glycol plastic blister pack and sealed with a labeled Tyvek® blister backer. When applied to the skin, the adhesive is distributed through the applicator tip in a syrup-like viscosity and polymerizes within minutes. The increased viscosity in **Exofin®** High Viscosity Topical Skin Adhesive is intended to reduce the risk of unintended placement of the adhesive during application due to migration of the liquid adhesive from the wound site. In-vitro studies have shown that **Exofin®** High Viscosity Topical Skin Adhesive acts as a barrier to microbial penetration when 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.

5. Intended Use

Exofin® High Viscosity Topical Skin Adhesive 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®** High Viscosity Topical Skin Adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

6. Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of **Exofin®** High Viscosity Topical Skin Adhesive and the predicate device are similar. Both devices:

- are 2-octyl cyanoacrylate-based, rapid polymerizing, liquid adhesive formulations
- contain D&C violet #2 colorant to aid in visualization during application
- provide an applicator tip that comprises of a connector, porous disk and soft elastomeric brush
- polymerizes within minutes of application
- maintain skin edge approximation and provide a microbial barrier
- are sterilized by a two-stage process with a sterility assurance level of 10^{-6}

In addition to a change to the proprietary name, the differences between **Exofin®** High Viscosity Topical Skin Adhesive and the predicate include:

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Traditional 510(k) for Exofin® High Viscosity Topical Skin Adhesive

- slight modification to the formulation
- increased viscosity

These differences do not raise different questions of safety and effectiveness.

7. Performance and Safety Data

Testing was performed in accordance with the FDA Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin.

Performance Testing

The following tests were performed on **Exofin®** High Viscosity Topical Skin Adhesive 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
- Hydrolytic Degradation
- Viscosity
- Microbial Barrier Properties
- Applicator Torque Strength and Expression Force
- Setting (Tack-Free) Time

In these studies, **Exofin®** High Viscosity Topical Skin Adhesive met all performance criteria.

Biocompatibility Testing

The biological evaluation of **Exofin®** High Viscosity Topical Skin Adhesive was performed in accordance with ISO 10993-1, "Biological Testing of Medical Devices – Part 1: Evaluation and testing within a risk management process " for a device intended for prolonged contact (>24 hours – 30 days) with breached or compromised skin surface. The results of the studies, listed below, demonstrate that **Exofin®** High Viscosity Topical Skin Adhesive is safe for its intended use.

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Systemic Toxicity Study and Local Tissue Response Following Full-Thickness Incisions in Rat, 14 days

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Traditional 510(k) for Exofin® High Viscosity Topical Skin Adhesive

8. Conclusion

Exofin® High Viscosity Topical Skin Adhesive was evaluated in accordance with the Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin. **Exofin®** High Viscosity Topical Skin Adhesive is substantially equivalent to Exofin® High Viscosity Tissue Adhesive with regard to indications for use, mechanism of action and performance characteristics. Both devices contain the same principle chemical ingredient, 2-Octyl cyanoacrylate. Both devices were shown to be equivalent in all performance and safety tests. Therefore, the slight change in formulation does not raise different questions of safety and effectiveness.