September 9, 2021

Chemence Medical, Inc.
Charnelle Thomas
Director of Regulatory Affairs
200 Technology Drive
Alpharetta, Georgia 30115

Re: K212246
Trade/Device Name: Exofin Precision Pen
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue Adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: August 9, 2021
Received: August 10, 2021

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,

Lixin Liu, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212246

Device Name
Exofin® Precision Pen

Indications for Use *(Describe)*
Exofin® Precision Pen 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® Precision Pen 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.

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

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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.
200 Technology Drive
Alpharetta, GA 30005-3926
Phone: 844-633-4583
Fax: 678-820-3320

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

Date of Summary: September 8, 2021

2. Device

Device Proprietary Name: Exofin® Precision Pen

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 Topical Skin Adhesive

510(k) Clearance: K200264

4. Device Description

Exofin® Precision Pen 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. The adhesive is provided in a 1.0g size, single-use, aluminum, collapsible tube that is fitted with a polyethylene-based applicator tip. The applicator tip consists of three components, a connector fitted with a self-puncturing cap, porous disc and soft elastomeric brush. The aluminum tube is housed within a silicone bulb that is connected to a polypropylene pen body and held by the end user during application. The adhesive, applicator tip, silicone bulb and pen body are packaged together in a (PETG) plastic blister pack and sealed with a labeled Tyvek® blister backer. A total of 12 units are packaged in a tray which is covered by a sleeve. 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 assists in the unintended placement of the adhesive during application due to migration of the liquid adhesive from the wound site. The silicone bulb and pen body of the **Exofin®** Precision Pen were designed to improve ergonomics during application. In-vitro studies have shown that **Exofin®** Precision Pen acts as a barrier to microbial penetration when the adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties.

5. Intended Use

Exofin® Precision Pen 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®** Precision Pen may be used in conjunction with, but not in place of, deep dermal sutures.

6. Comparison of Technological Characteristics with the Predicate Device

Most technological characteristics of **Exofin®** Precision Pen and the predicate device are the same. 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 disc and soft elastomeric brush
- polymerizes within minutes of application
- maintain skin edge approximation and provide a bacterial barrier
- are sterilized by a two-stage process with a sterility assurance level of 10^{-6}

The difference between **Exofin®** Precision Pen and the predicate is the addition of a pen (silicone bulb and pen body) for improved ergonomics during application and a change to increase the blister size to accommodate the pen body. Additionally, there is an increase in the number of device units in each tray from 10 to 12. The adhesive formulation, aluminum tube and applicator tip remain unchanged from the predicate device, Exofin High Viscosity Topical Skin Adhesive (K200264). These differences do not raise different questions of safety and effectiveness.

7. Performance 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®** Precision Pen to demonstrate substantial equivalence:

- Mechanical Applicator Testing

In these studies, **Exofin®** Precision Pen met all performance criteria. Because the adhesive, aluminum tube and applicator tip remain unchanged, no additional performance test were done.

Biocompatibility Testing

The pen of subject device does not come into direct or indirect contact with the patient or adhesive, therefore,biocompatibility is not required. Because the adhesive is unchanged, no additional biocompatibility tests were performed.

Sterilization and Shelf Life

Exofin® Precision Pen is sterilized in a two-step process by dry heat and ethylene oxide gas at a sterility assurance level (SAL) of 10^{-6}. The shelf life of the device has been determined through both real time and accelerated aging studies. The data from these studies support a 12-month shelf-life.

8. Conclusion

Exofin® Precision Pen was evaluated in accordance with the Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin. **Exofin®** Precision Pen is substantially equivalent to Exofin® High Viscosity Topical Skin 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 performance testing. Therefore, the change of adding a silicone bulb and pen body, for improved ergonomics during application and a change to packaging dimensions to accommodate the pen size, do not raise different questions of safety and effectiveness.