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.