DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 25, 2017

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

Re: K171442
Trade/Device Name: Exofin Fusion Skin Closure System
Regulation Number: 21 CFR 878.4011
Regulation Name: Tissue adhesive with adjunct wound closure device intended for topical approximation of skin
Regulatory Class: Class II
Product Code: OMD
Dated: August 24, 2017
Received: August 25, 2017

Dear Dr. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171442

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 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.

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
(In accordance with 21 CFR 807.92)

Chemence Medical, Inc.
Exofin® Fusion Skin Closure System

1. Submitter

Submitted by: Chemence Medical, Inc.
200 Technology Drive
Alpharetta, GA 3005-3926
Phone: 844-633-4583
Fax: 678-820-3320

Contact Person: Dr. Kenneth N. Broadley
Executive Vice President
Chemence Medical, Inc.

Date of Summary: September 25th, 2017

2. Device

Device Trade Name:	Exofin® Fusion Skin Closure System
Common Name:	Topical Tissue 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

3. Predicate Device

Legally marketed device to which equivalence is claimed:

Device Name:	Dermabond™ Prineo™ Skin Closure System
510(k) Clearance:	K133864 and K082289

4. 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 aluminum collapsible tube packaged in a RXM 48gaPET-200LDPE Film/1059B uncoated Tyvek pouch containing an applicator. The applicator is comprised of a self-puncturing cap and a soft elastomeric brush, which allows the adhesive to spread uniformly. As applied to skin, the liquid is syrup-like in viscosity and polymerizes within minutes. Exofin® Fusion Skin Closure System has a low viscosity. *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 two incisions up to 20 cm each in length until the liquid adhesive is applied to achieve skin closure.

5. 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.

6. Comparison of Technological Characteristics with the Predicate Device.

Exofin® Fusion® Skin Closure System is very similar to Dermabond™ Prineo™ Skin Closure System 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 up to 20 cm in length until the liquid topical adhesive is applied to achieve wound closure. Both liquid adhesives have the same principle ingredient, 2-octylcyanoacrylate. The Exofin® Fusion® Skin Closure System has two mesh strips of 22 cm in length by 4 cm in width. The Dermabond™ Prineo™ Skin Closure System come in two configurations, one which contains one mesh strip of the same dimensions and another with a dispenser for the mesh tape which is 60 cm in length.

7. Performance Data

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.

Performance Testing

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
- Degradation rate
- Viscosity
- Microbial barrier properties

Biocompatibility Testing

The biological evaluation of exofin® Fusion Skin Closure System was performed in accordance with ISO 10993-1, "Biological Testing of Medical Devices – Part 1: Evaluation and testing within a risk management process. The following test reports were provided in this submission:

- Cytotoxicity
- Intracutaneous irritation
- Sensitization
- Implantation
- Systemic Toxicity

A porcine wound healing study was performed to compare Dermabond™ Prineo™ Skin Closure System and the Exofin® Fusion Skin Closure System in terms of their respective effectiveness and their impact on the progression of wound healing over the course of 14 days. Extensive histological analysis showed that healing progressed normally during the course of the study. Dermabond™ Prineo™ Skin Closure System and the Exofin® Fusion Skin Closure System were considered to be substantially equivalent in terms of their performance and safety during the course of this study.

Sterilization and Shelf Life

Exofin® Fusion Skin Closure System is sterilized by dry heat and ethylene oxide gas. The shelf life of the device has been determined through both real time and accelerated aging studies.

8. Conclusion

Based on the intended use, technological characteristics, safety and performance testing, Exofin® Fusion Skin Closure System has been shown to be substantially equivalent to the Dermabond™ Prineo™ Skin Closure System.