



Food and Drug Administration
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February 9, 2016

Chemence Medical Products, Inc.
Kenneth Broadley, Ph.D.
Vice President Regulatory Affairs, Quality Assurance and NPD
200 Technology Drive
Alpharetta, Georgia 30005

Re: K152476

Trade/Device Name: Exofin High Viscosity Tissue Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: January 13, 2016
Received: January 14, 2016

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 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" (21CFR 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 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 yours,

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

Indications for Use

510(k) Number (if known)

K152476

Device Name

Exofin® High Viscosity Tissue Adhesive

Indications for Use (Describe)

Exofin® High Viscosity Tissue 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 Tissue 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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**510(k) Summary
(In accordance with 21 CFR 807.92)**

**Chemence Medical, Inc.
Exofin® High Viscosity Tissue Adhesive**

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
Vice President
Regulatory Affairs, Quality Assurance and
New Product Development
Chemence Medical, Inc.

Date of Summary: February 4th, 2016

2. Device

Device Trade Name: Exofin® High Viscosity Tissue 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 Devices

Legally marketed devices to which equivalence is claimed:

Device Name: Derma+Flex QS Tissue Adhesive
510(k) Clearance: K101276

Device Name: Dermabond NX Topical Skin Adhesive
510(k) Clearance: K100423



4. Device Description:

Exofin[®] High Viscosity Tissue Adhesive 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**[®] High Viscosity Tissue Adhesive has a syrup-like viscosity. The increased viscosity in **Exofin**[®] 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 Tissue Adhesive 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.

5. Intended Use:

Exofin[®] High Viscosity Tissue 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 Tissue Adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

6. Comparison of Technological Characteristics with the Predicate Device.

Exofin[®] High Viscosity Tissue Adhesive is very similar to Dermabond NX Topical Skin Adhesive and derma+flex QS with regard to intended use, mechanism of action and performance characteristics. All devices contain the same principle chemical ingredient, 2-octyl cyanoacrylate. **Exofin**[®] High Viscosity Tissue Adhesive has a different applicator from either of the two predicates and also has a larger volume of adhesive.

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® High Viscosity Tissue 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 F2258-05)
- Heat of polymerization
- Degradation rate
- Viscosity
- Microbial barrier properties

Biocompatibility Testing

The biological evaluation of Exofin® High Viscosity Tissue Adhesive 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

Under the conditions of the studies, Exofin® High Viscosity Tissue Adhesive was considered to be non-cytotoxic, non-irritating and non-sensitizing.

Sterilization and Shelf Life

Exofin® High Viscosity Tissue Adhesive 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 testing carried out, Exofin® High Viscosity Tissue Adhesive is substantially equivalent to the predicate devices.