DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 22, 2016

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

Re: K162352
Trade/Device Name: derma+flex QS High Viscosity Tissue Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: November 21, 2016
Received: November 22, 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,

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)*
K162352

Device Name
derma+flex® QS™

Indications for Use *(Describe)*

derma+flex® QS ™ 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.
derma+flex® QS ™ 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.

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

Chemence Medical, Inc.
Derma+flex® QS™ 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
Executive Vice President

Date of Summary: December 20th, 2016

2. Device

Device Trade Name: derma+flex® QS™ 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

Proprietary Name: derma+flex® QS™
510(k) Clearance: K101276

4. Device Description

derma+flex® QS™ 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/1095B uncoated Tyvek pouch also containing 2 Indothene HD Grade HD50MA 180 applicator tips. The dauber applicator is comprised of a self-puncturing cap and a foam surface, which allows spreading of the adhesive with uniformity.
The nozzle applicator is also a self-puncturing cap with an elongation that enables detailed application of the adhesive. As applied to the skin, the liquid is syrup-like in viscosity and polymerizes within minutes. The increased viscosity of derma+flex® QS™ 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.

5. Intended Use:

derma+flex® QS™ High Viscosity Tissue Adhesive is intended for topical application only to hold closed easily approximated skin edges of wounds from surgical incision, including incisions from minimally invasive surgery, and simple, thorough cleansed, trauma-induced lacerations. **derma+flex® QS™** High Viscosity Tissue Adhesive may be used in conjunction with, but not in place of, deep dermal sutures.

6. Comparison of Technological Characteristics with Predicate

derma+flex® QS™ High Viscosity Tissue Adhesive is practically identical to the predicate with regards to Indication for use, formulation, technology, target population, intended application, mechanism of action and performance at achieving their intended use. Both devices present that same main chemical characteristics (2-Octyl Cyanoacrylate) and the same formulating materials. The minor differences between **derma+flex® QS™** High Viscosity Tissue Adhesive and the predicate center around the sterilization processes. Like the predicate, derma+flex® QS™ is sterilized in two steps during the production process involving dry heat and ethylene oxide to a Sterility Assurance Level of 10^{-6}. While the sterilizing agents are the same the conditions have been changed. These differences do not raise new questions of safety and effectiveness.

7. Shelf-Life.

Shelf-life studies were performed to show that the minor differences in sterilization conditions did not change the performance of the device over time. Testing included:

Wound Closure Strength (according to ASTM F2458-05)

Tensile Strength (according to ASTM F2258-05)
T-Peel Strength (according to ASTM F2256 -05)
Lap Shear Strength (according to ASTM F2255-05)

Viscosity
Polymerization Time
Purity
Water Content

8. Conclusion

Based on the studies carried out, the minor changes in the sterilization process between derma+flex® QS™ and the predicate device have not altered its performance indicating derma+flex® QS™ High Viscosity Tissue Adhesive is substantially equivalent to the predicate.