July 15, 2024

Connexicon Medical Ltd.
Martin Brennan
Director of Quality and Regulatory Affairs
Synergy Centre
Institute of Technology Tallaght (ITT)
Dublin, Dublin D24 A386
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Re: K233458
Trade/Device Name: CM005 Standard (CM005); CM004 Mini (CM004)
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue Adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: June 11, 2024
Received: June 13, 2024

Dear Martin Brennan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

FDA Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical
and Infection Control Devices
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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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233458

Device Name

CM005 Standard (CM005);
CM004 Mini (CM004)

Indications for Use *(Describe)*

The indication for use for both devices is shown below:

CM005 Standard Topical Skin Adhesive is indicated 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. CM005 STANDARD Topical Skin Adhesive may be used in conjunction with, but not in place of deep dermal stitches. CM005 STANDARD Topical Skin Adhesive should be applied by trained medical or nursing staff.

CM004 Mini Topical Skin Adhesive is indicated 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. CM004 Mini Topical Skin Adhesive may be used in conjunction with, but not in place of deep dermal stitches. CM004 Mini Topical Skin Adhesive should be applied by trained medical or nursing staff.

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.

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510(k) Summary

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Contact Person: Martin Brennan
Director of Quality and Regulatory Affairs

Date of Summary: 15 July 2024

Device Name: CM005 Standard Topical Skin Adhesive and CM004 Mini Topical Skin Adhesive

Common Name: Topical Skin Adhesive

Classification Name: Tissue adhesive for the Topical Approximation of Skin

Regulatory Number: 21 CFR 878.4010

Device Class: Class II

Product Code: MPN

Predicate Devices

Device Name: DERMABOND Advanced™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive

510(k) Clearance: K152096

Device Description CM005 Standard

CM005 Standard Topical Skin Adhesive is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet No. 2. It is provided as a single-use applicator in a blister package. The pen style applicator is composed of a crushable glass ampoule contained within a plastic tube and plastic enclosure with silicone brush tip. When applied to the skin, the liquid adhesive polymerizes within minutes. In vitro studies have

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shown that following application and polymerization, CM005 STANDARD Topical Skin Adhesive acts as a physical barrier to prevent 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.

Device Description CM004 Mini

CM004 Mini Topical Skin Adhesive is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet No. 2 It is provided in a single-use applicator packaged in a blister pack. The applicator is comprised of a crushable glass ampoule contained within a plastic tube and plastic enclosure with silicone brush tip. When applied to the skin, the liquid adhesive polymerizes within minutes. In vitro studies have shown that following polymerization, CM004 Mini Topical Skin Adhesive acts as a physical 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.

Indications for Use CM005 Standard

CM005 Standard Topical Skin Adhesive is indicated 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. CM005 Standard Topical Skin Adhesive may be used in conjunction with, but not in place of deep dermal stitches. CM005 Standard Topical Skin Adhesive should be applied by trained medical or nursing staff.

Indications for Use CM004 Mini

CM004 Mini Topical Skin 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. CM004 Mini Topical Skin Adhesive may be used in conjunction with, but not in place of deep dermal stitches. CM004 Mini Topical Skin Adhesive should be applied by trained medical or nursing staff.

Comparison of Technological Characteristics with the Predicate Device

The technological characteristics of the CM005 Standard Topical Skin Adhesive and CM004 Mini Topical Skin Adhesive and the predicate devices are similar, in that they all contain the same technological characteristics:

- **Adhesive**: 2-octyl cyanoacrylate based adhesive with D&C Violet #2 colorant
- **Accelerant**: Quaternary ammonium salt
- **Applicator**: Sterile single use applicator

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Differences compared to the Predicate Device

Use	The indications for use of the subject devices specify that the adhesive should be applied by trained medical or nursing staff. The difference is not critical as both the subject and predicate device are prescription devices, and both are indicated as such throughout the labelling.
Technology	The CM004 Mini has a silicone brush tip compared to the predicate device (High Viscosity DERMABOND® Mini Topical Skin Adhesive) which has a plastic tip. The silicone brush tip allows for adhesive control during application. Performance testing found that the subject device is substantially equivalent to the predicate device and this difference does not affect safety or efficacy.
Performance	It was determined through the testing (Bench and Animal) performed in this 510(k) submission, that the subject devices are substantially equivalent to the predicate devices and any minor differences in performance does not affect safety or efficacy.

Performance Data

Testing was performed in accordance with the FDA special controls guidance document for "Tissue Adhesive for the Topical Approximation of Skin - Class II Special Controls Guidance for Industry and FDA Staff".

Performance Testing

The following tests were performed on the both the CM005 Standard Topical Skin Adhesive and CM004 Mini Topical Skin Adhesive to demonstrate substantial equivalence to the respective predicate devices:

- Lap-shear strength (ASTM F2255-05)
- T-peel adhesion strength (ASTM F2256-05)
- Adhesive strength in tension (ASTM F2258-05)
- Wound closure strength (ASTM F2458-05)
- Adhesive degradation study
- Heat of polymerization
- Viscosity
- Set time
- Microbial barrier testing
- Device Yield and Quality of Film
- Flow Control
- Animal wound healing study

Biocompatibility

The biological evaluation of CM005 Standard Topical Skin Adhesive and CM004 Mini Topical Skin Adhesive was performed in accordance with FDA guidance on the use of ISO 10993-1. The following test reports were provided in this submission:

- Physical and/or chemical information: Solvent compatibility, Chemical characterization, and Toxicological risk assessment.
- Cytotoxicity.
- Sensitization.
- Intracutaneous reactivity.

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- Material mediated pyrogenicity.
- Acute toxicity
- Subacute toxicity
- Implantation

Conclusions

Based on the intended use, technological characteristics, safety and performance testing, CM005 Standard Topical Skin Adhesive and CM004 Mini Topical Skin Adhesive has been demonstrated to be substantially equivalent the respective predicate devices, DERMABOND Advanced™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive.