December 7, 2021

Ethicon, Inc.
Noorhidayah Norizan
Sr. Regulatory Affairs Program Lead
1000 Rte. 202 South
Raritan, New Jersey 08869

Re: K213512
Trade/Device Name: DERMABOND PRINEO Skin Closure System
Regulation Number: 21 CFR 878.4011
Regulation Name: Tissue Adhesive With Adjunct Wound Closure Device For Topical Approximation Of Skin
Regulatory Class: Class II
Product Code: OMD
Dated: November 1, 2021
Received: November 2, 2021

Dear Noorhidayah Norizan:

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. 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 located 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.

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

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 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,

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213512

Device Name
DERMABOND™ PRINEO™ Skin Closure System (CLR222US)

Indications for Use *(Describe)*
DERMABOND™ PRINEO™ 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. DERMABOND™ PRINEO™ 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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ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

510(k) Summary

Contact Details

Applicant Name: Ethicon, Inc.
Applicant Address: 1000 Rte. 202 South Raritan NJ 08869 United States
Applicant Contact Telephone: 908-800-6624
Applicant Contact: Ms. Noorhidayah Norizan
Applicant Contact Email: nnoriza@its.jnj.com

Device Name

Device Trade Name: DERMABOND™ PRINEO™ Skin Closure System
Common Name: Tissue adhesive with adjunct wound closure device for topical approximation of skin
Class: II
Classification Name: Cutaneous Tissue Adhesive with Mesh
Regulation Number: 878.4011
Product Code: OMD

Date Prepared: December 06, 2021

Legally Marketed Predicate Devices:

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K133864	DERMABOND™ PRINEO™ Skin Closure System	OMD

Device Description:

DERMABOND™ PRINEO™ Skin Closure System is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and colorant D & C Violet No. 2. It is provided in a single-use applicator packaged in a rigid blister. The applicator is composed of a crushable glass ampule contained within a pen applicator with an attached applicator tip. As applied to skin, the liquid topical skin adhesive is slightly more viscous than water and polymerizes within minutes. *In vitro* studies have shown that DERMABOND PRINEO 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.

DERMABOND PRINEO also incorporates a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment of incisions up to 20 cm in length until the liquid topical skin adhesive is applied to achieve skin closure.

Intended Use/Indications for Use

DERMABOND™ PRINEO™ 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. DERMABOND™ PRINEO™ 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.

Indications for Use Comparison

Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] has been followed and it was determined that subject DERMABOND PRINEO Skin Closure System is substantially equivalent to the predicate DERMABOND PRINEO Skin Closure System in that they share the same indications for use.

Technological Comparison:

Guidance for Industry and Food and Drug Administration Staff: The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] has been followed and it was determined that subject DERMABOND PRINEO Skin Closure System is substantially equivalent to the predicate DERMABOND PRINEO Skin Closure System in that they share:

a) the same fundamental scientific technology,
b) the same intended use,
c) the same design,
d) the same materials,
e) the same packaging materials and configuration,
f) the same labeling components
g) the same sterilization process (Dry Heat & Ethylene Oxide)
h) the same sterility assurance level (SAL) is 10^{-6}.

Non-Clinical and/or Clinical Tests Summary & Conclusion:

This section is not applicable, as both nonclinical and clinical testing are not necessary to support substantial equivalence since there have been no changes to the technological characteristics of the devices, including the adhesive formulation, design, material and performance; this change is only to reduce adhesive volume for subject device.

Based on the intended use, technological characteristics, safety and performance testing, the subject DERMABOND™ PRINEO™ Skin Closure System with lower adhesive volume has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the predicate DERMABOND™ PRINEO™ Skin Closure System (K133864).