DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 21, 2017

Ethicon, LLC
Mr. Joice Pappan
Regulatory Specialist II
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K163645
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: January 20, 2017
Received: January 23, 2017

Dear Mr. Pappan:

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" (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 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)*
K163645

Device Name
DERMABOND™ PRINEO™ Skin Closure System

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.

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ETHICON
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

510(k) Summary

Submitter: Ethicon Inc. a Johnson & Johnson company
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Date Prepared: April 19, 2017

Device Trade Name: DERMABOND™ PRINEO™ Skin Closure System

Device Common Name: Topical Skin Adhesive

Class: II

Classification Name: Tissue adhesive with adjunct wound closure device intended for the topical approximation of skin (21 CFR 878.4011)

Product Code: OMD

Predicate Devices:

Device	Company	Product Code	510(k) Number	Predicate for:
DERMABOND™ PRINEO™ Skin Closure System	Ethicon, Inc.	OMD	K133864	Fundamental Scientific Technology, Design, Intended Use, Materials, Construction, Performance Characteristics

Device Description:

DERMABOND™ PRINEO™ Skin Closure System is a sterile, liquid topical skin adhesive containing a monomeric (2-octylcyanoacrylate) formulation and the 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 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™ System also incorporates 2 self-adhering meshes that are applied to the approximated skin edges to provide temporary skin edge alignment of incisions up to 40 cm in length until the liquid adhesive is applied to achieve skin closure.

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.

Summary of Technological Characteristics and Performance Testing:

The safety and effectiveness of the subject device DERMABOND™ PRINEO™ Skin Closure System (DP42) and the substantial equivalence to the predicate device DERMABOND™ PRINEO™ Skin Closure System (DP22) has been demonstrated via data collected in non-clinical

design verification. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing. All materials used in the proposed device are the same to the predicate device and meet the requirements of ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and Testing within a risk management process.

The following tests were completed for the DERMABOND™ PRINEO™ Skin Closure System (42cm):

Biocompatibility/*In vivo*Testing	**Bench Testing**
Irritation (Intracutaneous Reactivity)	Creep Strength
Irritation (Modified ISO Skin)	Peel Strength- mesh only (N/cm)
Sensitization (ISO Guinea Pig Maximization)	Peel adhesion Strength-Mesh with adhesive (N/cm)
14 day Porcine Effectiveness Study	Wound/Tissue holding Strength (lbf)
	Set Time (Seconds)
	Set Temperature (°C)

Summary of Substantial Equivalence Comparison:

The subject DERMABOND™ PRINEO™ Skin Closure System (42 cm) is equivalent to the predicate DERMABOND™ PRINEO™ Skin Closure System (22 cm) described in K133864 with the exception of number of mesh patches. The subject device is intended to hold closed incisions up to 40 cm in length and the predicate device is for incisions up to 20 cm in length. The subject device has the same fundamental scientific technology and intended use as the current, legally marketed DERMABOND™ PRINEO™ Skin Closure System (22cm). The subject and predicate devices share the same materials, design, fundamental scientific technology (operating principle), labeling components, packaging materials and configuration and sterilization process. The additional size meets the same requirements as the current FDA cleared K133864 device.

Conclusion:

Based on the intended use, technological characteristics, safety and performance testing, the additional size of DERMABOND™ PRINEO™ Skin Closure System (42cm) has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the DERMABOND™ PRINEO™ Skin Closure System (22cm) (K133864).