510(k) K133864
DERMABOND™ PRINEO™ Skin Closure System
Ethicon, Inc.

MAR 1 0 2014

ETHICON, INC.
a Johnson & Johnson company

# 510(k) Summary

**Submitter:**
Ethicon Inc. a Johnson & Johnson company
P.O. Box 151
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Somerville, NJ 08876-0151

**Contact Person:**
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Manager, Regulatory Affairs
Ethicon, Inc. a Johnson & Johnson company
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**Date Prepared:** December 18, 2013

**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

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**Predicate Device:**

| Device | Company | Product Code | 510(k) Number | Predicate for |
|---|---|---|---|---|
| DERMABOND™ PRINEO™ Skin Closure System | Ethicon, Inc. | OMD | K082289 | 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-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 acts as a barrier to microbial penetration as long as the liquid topical skin 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.

**Indications for Use:**

DERMABOND PRINEO Skin Closure 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 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 DERMABOND™ PRINEO™ Skin Closure System and the substantial equivalence to the predicate device 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 as 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.

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Below you will find a list of non-clinical performance data completed for the DERMABOND™ PRINEO™ Skin Closure System:

| **Bench Testing** | **Bench Testing (continued)** | **Biocompatibility/In vivoTesting** |
|---|---|---|
| Peel Test | Systematic Hydrolytic Extraction (SHE) | Cytotoxicity (ISO Elution) |
| Creep Test | Water Vapor Transmission Rate | Irritation (Intracutaneous Reactivity) |
| Tensile Strength | Adhesive Applicator Dial Torque, Expression Force, And Dispensed Volume | Irritation (Modified ISO Skin) |
| Peel Adhesion Strength Test | Reliability of Adhesive Applicator Mechanism | Sensitization (ISO Guinea Pig Maximization) |
| Setting Performance | Adhesive Applicator Drip Test | Acute Systemic Toxicity (IP injection) |
| Liner Paper Peel Strength Release | | Pyrogenicity (Material Mediated) |
| Shelf Life | **Packaging Testing** | Intramuscular Implantation |
| Viscosity | Package Seal Strength | Primary Ocular Irritation (Draize) |
| Purity/Impurity by GC | Seal Integrity | Modified Skin Draize Test |
| Microbial Barrier | Package Integrity | 14 day Porcine Effectiveness Study |

**Summary of Substantial Equivalence Comparison:**

The subject DERMABOND™ PRINEO™ Skin Closure System is equivalent to the predicate DERMABOND™ PRINEO™ Skin Closure System described in 510(k) #K082289 with the exception of the size of the mesh patch. The subject device is intended to hold closed incisions up to 20 cm in length and the predicate device is for incisions up to 60 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. The subject and predicate devices share the same materials, design, fundamental scientific technology (operating principle), labeling components, packaging materials and configuration, shelf life and sterilization process. The additional size meets the same requirements as the current FDA cleared [510(k) K082289] device.

**Conclusion:**

Based on the intended use, technological characteristics, safety and performance testing, the additional size of DERMABOND™ PRINEO™ Skin Closure System has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the DERMABOND™ PRINEO™ Skin Closure System (K082289).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

March 10, 2014

Ethicon, Inc.
Donna Marshall
Manager, Regulatory Affairs
P.O. Box 151, Route 22 West
Somerville, New Jersey 08876-0151

Re: K133864
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: February 07, 2014
Received: February 10, 2014

Dear Ms. Marshall:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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 Ashar, MD, MBA, FACS
Acting 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 on last page.*

510(k) Number *(if known)*
K133864

Device Name
DERMABOND™ PRINEO™ Skin Closure System

Indications for Use *(Describe)*
DERMABOND PRINEO Skin Closure 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 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)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S