



Food and Drug Administration  
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Silver Spring, MD 20993-0002

November 25, 2015

ETHICON, Inc.  
Donna Marshall  
Manager, Regulatory Affairs  
Route 22 West, P.O. Box 151,  
Somerville, NJ 08876-0151

Re: K152490

Trade/Device Name: DERMABOND PRINEO Skin Closure System  
Regulation Number: 21 CFR 878.4011  
Regulation Name: Tissue Adhesive with Adjunct Wound Closure  
Regulatory Class: Class II  
Product Code: OMD  
Dated: August 31, 2015  
Received: September 1, 2015

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 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 yours,

**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

## Indications for Use

510(k) Number (if known)

K152490

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

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## 510(k) Summary

**Submitter:** Ethicon, Inc. a Johnson & Johnson company  
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USA

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**Date Prepared:** August 31, 2015

**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 topical approximation of skin (21 CFR 878.4011)

**Product Code:** OMD

Predicate Device	510(k) Number
DERMABOND™ PRINEO™ Skin Closure System	K082289/DEN090005
DERMABOND™ PRINEO™ Skin Closure System	K133864

**Device Description:**

DERMABOND™ PRINEO™ Skin Closure System 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 rigid blister. The applicator is composed of a crushable glass ampule contained within a pen applicator with 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 liquid adhesive film remains intact. Clinical studies were not conducted to demonstrate microbial barrier properties.

DERMABOND™ PRINEO™ System also incorporates a self-adhering mesh that is applied to the approximated skin edges to provide temporary skin edge alignment 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:**

DERMABOND™ PRINEO™ System is identical to the DERMABOND™ PRINEO™ System (K082289/DEN090005) marketed device with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed devices. The devices differ only in the labeling (Instructions for Use) that have been revised to add a contraindication, as well as other clarifications to ensure safer, more effective use of the device.

**Substantial Equivalence:**

DERMABOND™ PRINEO™ System is identical to the DERMABOND™ PRINEO™ System marketed device with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed devices. The devices differ only in the labeling (Instructions for Use) that have been revised to add a contraindication, as well as other clarifications to ensure safer, more effective use of the device.

**Conclusion:**

DERMABOND™ PRINEO™ System is identical to the DERMABOND™ PRINEO™ System marketed device with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed devices. DERMABOND™ PRINEO™ is considered to be substantially equivalent to the predicate device.