DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 22, 2015

Ethicon Incorporated
Ms. Donna Marshall
Regulatory Affairs Manager
Route 22 West, P.O. Box 151
Somerville, New Jersey 08876

Re: K152096
Trade/Device Name: DERMABOND Advanced™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: July 27, 2015
Received: July 28, 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

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)*

K152096

Device Name

DERMABOND Advanced™ Topical Skin Adhesive

Indications for Use *(Describe)*

DERMABOND ADVANCED™ 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. DERMABOND ADVANCED™ Adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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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)*

K152096

Device Name

High Viscosity DERMABOND® Mini Topical Skin Adhesive

Indications for Use *(Describe)*

High viscosity DERMABOND® Adhesive 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. High viscosity DERMABOND® Adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

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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USA

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Date Prepared: July 27, 2015

Device Trade Name: **DERMABOND ADVANCED™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive**

Device Common Name: Topical Skin Adhesive

Class: II

Classification Name: Tissue Adhesive for the Topical Approximation of Skin (21 CFR 878.4010)

Product Code: MPN

Predicate Device	510(k) Number
DERMABOND ADVANCED™ Topical Skin Adhesive	K100423
High Viscosity DERMABOND® Mini Topical Skin Adhesive	P960052

Device Description DERMABOND ADVANCED™:

DERMABOND ADVANCED™ 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 ampoule contained within a plastic applicator. As it is applied to the skin, the liquid is syrup-like in viscosity and polymerizes within minutes. Studies have shown that following application, DERMABOND ADVANCED™ Adhesive acts as a barrier to prevent microbial penetration as long as the adhesive remains.

Device Description High Viscosity DERMABOND® Mini Topical Skin Adhesive:

High viscosity DERMABOND® Topical Skin Adhesive is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation and the colorant D & C Violet #2. It is provided in a single-use applicator packaged in a blister pouch. The applicator is composed of a crushable glass ampule contained within a plastic vial with attached applicator tip. As applied to skin, the liquid is syrup-like in viscosity and polymerizes within minutes. *In vitro* studies have shown that high viscosity DERMABOND® Adhesive 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.

High viscosity DERMABOND® Adhesive is different from the regular, or low viscosity DERMABOND® Adhesive due to the increased viscosity of the liquid adhesive formulation. Low viscosity DERMABOND® Adhesive has a viscosity slightly greater than water, while high viscosity DERMABOND® Adhesive has a syrup-like viscosity. The increased viscosity of high viscosity DERMABOND® Adhesive is intended to reduce the risk of unintended placement of the adhesive during application due to migration of the liquid adhesive from the wound site.

Indications for Use DERMABOND ADVANCED:

DERMABOND ADVANCED™ 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. DERMABOND ADVANCED™ Adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

Indications for Use High Viscosity DERMABOND® Mini Topical Skin Adhesive:

High viscosity DERMABOND® Adhesive 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. High viscosity DERMABOND® Adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

Summary of Technological Characteristics:

DERMABOND ADVANCED™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive are identical to the DERMABOND ADVANCED™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive 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 ADVANCED™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive are identical to the DERMABOND ADVANCED™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive 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 ADVANCED™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive are identical to the DERMABOND ADVANCED™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive marketed device with respect to technological characteristics. There are no material, construction, specification, manufacturing or sterilization process changes to the currently marketed devices. DERMABOND ADVANCED™ Topical Skin Adhesive and High Viscosity DERMABOND® Mini Topical Skin Adhesive are considered to be substantially equivalent to the predicate devices.