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K100423

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Section 5. 510(k) Summary as required by 21 CFR 807.92(c)

510(k) Owner: **Ethicon, Inc.**
P.O. Box 151, Route 22 West
Somerville, NJ 08876-0151
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Contact Person: Neelu Medhekar, WW Director, Regulatory Affairs, Ethicon Products

Date: February 1, 2010

Trade Name: DERMABOND® NX Topical Skin Adhesive

Common Name: Topical Skin Adhesive

Classification Name: Tissue Adhesive for the Topical Approximation of Skin

Product Code: MPN

Predicate Device: DERMABOND® Topical Skin Adhesive (P960052): Reclassified from Class III PMA to Class II 510(k) – May 5, 2008 – Docket number 2006p-071.

Device Description:

DERMABOND® NX Topical Skin Adhesive is a sterile, liquid topical skin adhesive containing a monomeric (2-octyl cyanoacrylate) formulation with a viscosity increasing agent, stabilizer, and colorant (D&C Violet #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 easily approximated skin edges in a single layer; the liquid is syrup-like in viscosity and polymerizes within minutes. Studies have shown that following application, DERMABOND NX Topical Skin Adhesive acts as a barrier to prevent microbial penetration.

Indications for Use:

DERMABOND® NX Topical Skin 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® NX Topical Skin Adhesive may be used in conjunction with, but not in place of, deep dermal stitches.

These indications for use are identical to those of Dermabond (predicate device).

Technological Characteristics:

The technological characteristics of DERMABOND NX Topical Skin Adhesive are equivalent in performance to the predicate device, DERMABOND Topical Skin Adhesive.

DERMABOND NX consists of a liquid topical skin adhesive formulation packaged within a dispensing applicator. The device is supplied in a sterile single-use package for use in wound closure procedures. DERMABOND NX is a higher viscosity formulation to allow precise application of the adhesive to the intended area and allow a single application of the adhesive to the wound area. The topical skin adhesive is designed to bond to the skin to provide flexible wound closure maintaining wound approximation and providing a microbial barrier.

The main difference between DERMABOND NX and the predicate device is the adjusted higher viscosity to allow a one pass application and a different compound to increase the heat dissipation, reducing heat generated during the adhesive curing process on the skin.

Determination of Substantial Equivalence:

1. **Biocompatibility**

The biocompatibility of DERMABOND NX Topical Skin Adhesive device has been evaluated through the use of the recommended biocompatibility tests. Tests included acute systemic toxicity, ocular irritation, primary skin irritation, Kligman sensitization, intracutaneous reactivity, subcutaneous implantation and MEM (cytotoxicity). The results were substantially equivalent to those of the predicate device.
These results are not substantially different when compared to the predicate device when the same procedures were used.

2. Performance Bench Testing:

All testing for DERMABOND NX Topical Skin Adhesive has been completed according to Design Control requirements of 21CFR820.30. The testing plan and results were based on the FDA guidance document "*Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin*". Bench tests included device activation force, compression force, expressed mass, wound burst strength, flatwise tensile and overlap shear testing, skin tensile and T-peel testing and water resistance testing. In all cases, DERMABOND NX met specifications and demonstrated equivalence to the predicate device with the minor changes of better heat dissipation and increased viscosity.

3. Sterilization and Shelf-Life:

Sterilization of DERMABOND NX Topical Skin Adhesive is the same as the predicate device, DERMABOND family of products (P960052). The sterilization process consists of two parts: 1) The dry heat sterilization of formulation filled ampoules containing liquid topical skin adhesive. And 2) The 100% ethylene oxide (EO) sterilization of the device after final packaging. Both of these processes provide a minimum sterility assurance level (SAL) of 10^{-6} which are the same as those used for sterilization of the predicate DERMABOND products.

Both real-time and accelerated stability testing data has been collected in support of this submission. Two years equivalent of accelerated testing has been completed supplementing the real time data of currently 12 months. Real time data will continue to be collected and analyzed to support a two (2) year shelf life labeling claim.

Based on extensive biocompatibility and bench testing, Dermabond NX has been demonstrated to be substantially equivalent to its predicate device from a safety perspective and has also demonstrated higher viscosity and better heat dissipation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ethicon, Inc.
% Ms. Neelu Medhekar
Director, Regulatory Affairs
P.O. Box 151, Route 22 West
Somerville, New Jersey 08876-0151

MAY - 4 2010

Re: K100423
Trade/Device Name: DERMABOND® NX Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: Class II
Product Code: MPN
Dated: February 05, 2010
Received: February 16, 2010

Dear Ms. Medhekar:

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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K100423

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Device Name: DERMABOND® NX Topical Skin Adhesive

Indications For Use:

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Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use NO (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100423