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 4, 2016

Bergen Medical Products, Inc.
Mr. Tom Stephens
Vice President, Regulatory Affairs and Quality Assurance
16 Wing Drive
Cedar Knolls, NJ 07927 US

Re: K161050
Trade/Device Name: ACTABOND Topical Skin Adhesive
Regulation Number: 21 CFR 878.4010
Regulation Name: Tissue adhesive
Regulatory Class: II
Product Code: MPN
Dated: September 1, 2016
Received: September 2, 2016

Dear Mr. Stephens:

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 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

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)*

K161050

Device Name

ACTABOND Topical Skin Adhesive

Indications for Use *(Describe)*

ACTABOND 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. ACTABOND Topical Skin 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.

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1. Submitter

Submitted by: Bergen Medical Products, Inc.
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Contact Person: Tom Stephens
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Phone: 855-855-3682 x703

Date of Summary: September 1, 2016

2. Device

Trade Name: ACTABOND™ Topical Skin Adhesive
Common or Usual Name: Topical skin adhesive
Classification Name: Tissue adhesive for the topical approximation of skin
Classification Panel: General and Plastic Surgery Devices
Regulation: 21 CFR 878.4010(a) – Class II
Product Code: MPN

3. Predicate Device

Device Name: DERMABOND® NX Topical Skin Adhesive (currently marketed as DERMABOND® Advanced Topical Skin Adhesive)
510(k) Clearance: K100423
Regulation: 21 CFR 878.4010(a) – Class II
Product Code: MPN

4. Device Description

ACTABOND Topical Skin Adhesive is a skin closure device that is comprised of a 2-octyl cyanoacrylate liquid adhesive formulation containing D & C Violet #2. The liquid adhesive is supplied sterile within a single use dispensing applicator, which is used to deliver the adhesive to the skin. Once applied, the liquid adhesive polymerizes to form a thin film with strong bonding and tensile properties. *In vitro* studies have shown that following application, ACTABOND Adhesive acts as a barrier to prevent bacterial penetration. The barrier properties of ACTABOND Adhesive have not been studied in clinical or animal models.

5. Indications for Use

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

6. Comparison of Technological Characteristics with Predicate

The technological characteristics of ACTABOND Topical Skin Adhesive and the predicate device are closely comparable. Both devices:

- are 2-octyl cyanoacrylate-based liquid adhesive formulations containing D&C violet #2
- are sterilized in their final packaging to an SAL of 10^{-6} using ethylene oxide
- provide a pen-style single use applicator that is delivered sterile in a peel open package
- incorporate a flexible bulb tip that is squeezed to apply the adhesive from the applicator
- polymerize within minutes to form a film with strong bonding and tensile properties
- maintain skin edge approximation and provide a bacterial barrier

The minor differences between the ACTABOND and DERMABOND devices include:

- different primary packaging
- different sterilization method for the adhesive in the primary packaging
- different applicator actuation mechanism that avoids glass shards

These differences do not raise new questions of safety and effectiveness.

7. Performance Data

The testing plan for the ACTABOND device was developed in consideration of the FDA guidance document “Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin”, May 30, 2008, as well as design control requirements and risk analysis. Testing to establish substantial equivalence of the ACTABOND Topical Skin Adhesive to the predicate device has been completed according to Bergen Medical procedures in compliance with the requirements of 21 CFR 820.30 – Design Control.

<u>Performance Testing:</u>
Bench studies have been performed to evaluate the device properties:

- Viscosity
- Setting time
- Purity
- Moisture
- Hydrolytic degradation
- Bacterial barrier

Performance studies have been performed to demonstrate equivalence to the predicate device. In all cases, the ACTABOND device demonstrated equivalence to the predicate.

- Wound closure strength (ASTM F2458-05)
- Tensile strength (ASTM F2258-05)
- Lap shear strength (ASTM F2255-05)
- Heat of polymerization
- Applicator Functionality

Animal Studies:

A porcine study was conducted to compare the safety and effectiveness of ACTABOND Topical Skin Adhesive to the predicate device in a surgically induced, full thickness, linear wound healing model. This study evaluated acute wound closure, maintenance of wound closure, and support of normal wound healing for 14 days. A histological evaluation was also performed to evaluate healing after 14 days.

The results of this study demonstrated no remarkable differences between the subject and predicate device study groups for clinical wound observations and histological analysis. Both groups maintained wound closure, supporting a normal wound healing process without delay and showed complete epidermal re-epithelialization at 14 days.

Biocompatibility:

The biocompatibility of the ACTABOND Topical Skin Adhesive device has been evaluated according to the studies recommended in AAMI/ANSI/ISO 10993-1:2009/(R)2013, "Biological evaluation of medical devices - part 1: Evaluation and testing within a risk management process" for a device intended for prolonged contact (24 hours – 30 days) with breached skin. The results of these studies, listed below, demonstrate that the ACTABOND Topical Skin Adhesive device is safe for its intended use.

- Cytotoxicity (ISO 10993-5:2009(R)2014)
- Irritation/Intracutaneous reactivity (ISO 10993-10:2010)
- Systemic Injection (ISO 10993-11:2006(R)2010)
- Sensitization/Kligman Maximization (ISO 10993-10:2010)
- Intramuscular implantation (ISO 10993-6:2007(R)2010)

Sterilization and Shelf-Life:

The ACTABOND device is sterilized in two steps during device production. The liquid adhesive formulation is sterilized in its primary packaging by electron beam radiation in compliance with the requirements of ISO 11137- 2:2013. After device assembly and packaging, the finished device is sterilized by exposure to ethylene oxide gas in compliance with the requirements of ISO 11135:2014. Both sterilization processes are validated to provide a Sterility Assurance Level of 10^{-6}. The shelf life of the device has been confirmed through real-time aging studies.

8. Conclusions

The ACTABOND Topical Skin Adhesive device and predicate device, DERMABOND NX Topical Skin Adhesive (K100423), have identical indications for use, function according to the same fundamental scientific technology, and are closely comparable with regard to device design. Minor differences between the ACTABOND device and the predicate with regard to the primary package for the adhesive, the sterilization method for the adhesive in its primary package, and the mechanism for device actuation do not raise different questions of safety or effectiveness. *In vitro* and *in vivo* testing results provided in the 510(k) submission demonstrate that the ACTABOND device meets its specifications and is substantially equivalent to the DERMABOND NX Topical Skin Adhesive predicate.