



Food and Drug Administration
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August 23, 2016

3M Healthcare
Ms. Maria Ruiz
Regulatory Affairs Specialist
3M Center
2510 Conway Avenue, Bldg. 275-5W-06
St. Paul, MN 55144

Re: K153571

Trade/Device Name: Cavilon Advanced Skin Protectant
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: Class I
Product Code: KMF
Dated: July 25, 2016
Received: July 27, 2016

Dear Ms. Ruiz:

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)

K153571

Device Name

3M™ Cavilon™ Advanced Skin Protectant

Indications for Use (Describe)

Cavilon™ Advanced Skin Protectant forms a film barrier intended to protect intact or damaged skin. It is effective in conditions where skin is frequently or continuously exposed to moisture and caustic irritants such as feces, digestive fluids, wound drainage and urine. Cavilon™ Advanced Skin Protectant also can be used in areas exposed to friction and shear from bedding, clothing, shoes or any other material that would rub against the skin.

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.

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510K SUMMARY**I. SUBMITTER**

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Date Prepared: December 4, 2015

II. DEVICE

Name of Device: 3M™ Cavilon™ Advanced Skin Protectant

Common or Usual Name: Barrier Film

Classification Name: Liquid Bandage

Regulatory Class: Class 1

Product Code: KMF per 21 CFR 880.5090

III. PREDICATE DEVICE

3M™ Cavilon™ No Sting Barrier Film (K955103)
Medline® Marathon® Liquid Skin Protectant (K133443)

IV. DEVICE DESCRIPTION

3M™ Cavilon™ Advanced Skin Protectant is a polymeric-cyanoacrylate solution intended for the protection of intact or damaged skin. Upon application to skin, the liquid dries rapidly to form a primary long-lasting waterproof, highly durable film barrier. It is elastomeric, adhering to the contours of the skin and providing a uniform film. The film is transparent and possesses good oxygen and moisture vapor permeability.

The polymer-cyanoacrylate is dispersed in a non-stinging solvent. The film is colorless and non-cytotoxic. The film adheres to dry, moist or wet skin surfaces and remains intact during conditions of continuous or repeated exposure to moisture or caustic irritants. It will wear off the skin and does not require removal.

V. INDICATIONS FOR USE

Cavilon™ Advanced Skin Protectant forms a film barrier intended to protect intact or damaged skin. It is effective in conditions where skin is frequently or continuously exposed to moisture and caustic irritants such as feces, digestive fluids, wound drainage and urine. Cavilon™ Advanced Skin Protectant also can be used in areas exposed to friction and shear from bedding, clothing, shoes or any other material that would rub against the skin.

The Indications for Use statement for Cavilon™ Advanced Skin Protectant is similar to the predicate devices. Both the Subject Device and predicate devices have the same intended use to form a liquid barrier film when applied to the skin, by providing a barrier against irritants and caustic substances (e.g., urine, fecal matter, digestive juices) and to reduce friction and shear from materials rubbing against the skin (e.g., bedsheets, clothing, shoes).

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological principle for the Subject Device and the predicate devices are that they are all liquid bandages. Just like its predicate devices, Cavilon™ Advanced Skin Protectant forms a transparent and durable barrier film to protect intact or damaged skin from the caustic effects of moisture, urine or feces and friction and shear. It is applied in liquid form to the area of interest on the skin and quickly polymerizes upon contact to form the barrier film.

The Subject Device and predicate devices all have similar technological elements which include:

- Operational principle
- Device is transparent
- Device provided in a liquid form
- Device forms a protective barrier
- Device is elastomeric
- Device is a durable barrier
- Device protects from friction
- Device is breathable

The minor differences do not raise different questions of safety and effectiveness. The following technological differences exist between the subject device and one or both of the predicate devices:

- Liquid technological components
- Monomer and/or polymer composition
- Device dries rapidly
- Device cures upon contact
- Delivery system
- Sterilization method

VII. PERFORMANCE DATA

The following performance data is provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for Cavilon™ Advanced Skin Protectant was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,’” as recognized by FDA. Cavilon™ Advanced Skin Protectant is characterized as a surface contacting device for use on breached or compromised skin for periods of time greater than 30 days. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Genotoxicity

Bench Testing

Bench testing for Cavilon™ Advanced Skin Protectant was conducted in support of substantial equivalence to the predicate devices. The bench testing included the following tests:

- Elongation
- Cure and/or Dry Time
- Friction
- Moisture Vapor Transmission Rate

Clinical Studies

Clinical testing of Cavilon™ Advanced Skin Protectant include:

- Controlled, randomized open label durability study on healthy subjects that demonstrated that Cavilon™ Advanced Skin Protectant is a durable barrier film that lasts up to 72 hours.
- Prospective, open label wash off resistance study on healthy subjects showed that the Cavilon™ Advanced Skin Protectant is similarly to Marathon® Liquid Skin Protectant with respect to the 'active' wash-off resistance and its ability to protect skin.

VIII. CONCLUSIONS

3M™ Cavilon™ Advanced Skin Protectant is substantially equivalent to the predicate devices, 3M™ Cavilon™ Barrier Film (K955103) and Medline Marathon® Liquid Skin Protectant (K133443).

Cavilon™ Advanced Skin Protectant is composed of similar components and similar performance, intended use and indications for use as the predicate devices.

Based on the similarities to the predicate devices, the minor differences do not present or raise any new safety or effectiveness issues and the device is substantially equivalent to the predicates.