June 27, 2019

Rochal Industries, LLC
William Coulston
Quality & Regulatory Manager
12000 Network Blvd, Ste B200
San Antonio, Texas 78249

Re: K182733
Trade/Device Name: Rochal Bioshield Silicone Film
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid Bandage
Regulatory Class: Class I
Product Code: KMF
Dated: May 24, 2019
Received: May 28, 2019

Dear Mr. William Coulston:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Cynthia Chang, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182733

Device Name
Rochal Bioshield Silicone Film

Indications for Use *(Describe)*
Rx: Bioshield Silicone Film is intended to cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions, as well as closed surgical incisions and excisions.

OTC: Bioshield Silicone Film is intended to help cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions.

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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510(k) Summary

1. **Submitter's Name and Address**
Rochal Industries LLC.
12000 Network Blvd, Ste B200
San Antonio, Texas, 78249

2. **Submitter's Contact Person**
William J. Coulston
Quality and Regulatory Manager
(210) 375-9349
wcoulston@rochalindustries.com

3. **Date of 510(k) Summary Preparation:**
June 26, 2019

4. **Device Name (Proprietary)**
Rochal® Bioshield Silicone Film

5. **Classification Name**
Bandage, Liquid

6. **Device Class and Regulation Number**
Class I, 21 CFR 880.5090

7. **Product Code**
KMF

8. **Predicate and Reference Devices:**
K131384 KeriCureTM Advanced Liquid Bandage, KeriCure Inc. (predicate device)
K955103 No Sting Barrier Film, 3M Medical Product Group (reference device)

9. **Description of Device**
Rochal Bioshield Silicone Film is a polymeric solution which forms a protective, polymer film (silicone) when applied to skin. The product is biocompatible and non-stinging. The formed silicone film is colorless, transparent, water-proof barrier, which is breathable, possessing good oxygen and moisture vapor permeability.

Rochal® Bioshield Silicone Film will be supplied in a High-Density Polyethylene (HDPE), 28 mL bottles with pump spray cap.

10. **Indications for Use**
Rochal® Bioshield Silicone Film is intended for prescription (Rx) and over-the-counter (OTC) uses as follows:

- Rx: Bioshield Silicone Film is intended to cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions, as well as closed surgical incisions and excisions.

- OTC: Bioshield Silicone Film is intended to help cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions.

11. Performance Testing

Rochal® Bioshield Silicone Film has been subjected to ISO 10993 biocompatibility studies (cytotoxicity, sensitization, irritation, pyrogenicity, implantation, chemical analysis and toxicological risk assessment) to demonstrate the device is as safe and as effective as its predicate device. The product is Gamma sterilized and sterility has been verified using USP 71, Sterility Tests. The results of real-time aging study indicate the product is stable and effective for the proposed shelf life.

12. Substantial Equivalence Discussion

Feature Being Compared	SUBJECT DEVICE K182733 Rochal® Bioshield Silicone Film	PREDICATE DEVICE K131384 KeriCureTM Advanced Liquid Bandage	REFERENCE DEVICE K955103 No Sting Barrier Film
Indications for Use	**Rx:** Rochal® Bioshield Silicone Film is intended to cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions, as well as closed surgical incisions and excisions. **OTC:** Bioshield Silicone Film is intended to help cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions.	**Rx:** KeriCure™ Advanced Liquid Bandage is intended to cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions, as well as closed surgical incisions and excisions. **OTC:** KeriCure™ Advanced Liquid Bandage is intended to help cover and protect the skin from infection in minor cuts, scrapes, burns, irritations and abrasions.	**OTC:** No Sting Barrier Film is a liquid intended for use as a film-forming product, that upon application to intact or damaged skin forms a long-lasting waterproof barrier, which acts as a protective interface between the skin and bodily wastes, fluids, adhesive products, and friction and shear. It is intended as a primary barrier against irritation from body fluids.
Product Film Appearance	Transparent film barrier	Transparent film barrier	Transparent film barrier
Functions	Non-stinging, breathable, water-proof barrier	Breathable, barrier	Non-stinging, water-proof barrier

As discussed in the 510(k) submission, Rochal® Bioshield Silicone Film has the same indications for use, and similar product form and function as the predicate device, KeriCure Advanced Liquid Bandage (K131384). The product formulation and technology are similar to the reference device, 3M No Sting Barrier Film (K955103). The safety evaluation meets the requirements as detailed by USP Chapter <151> and ISO 10993. The benefit-risk profile of the subject and predicate devices is similar, and any differences do not raise different questions regarding safety or effectiveness.

On the basis of the information presented in this 510(k) submission, Rochal Industries LLC, concludes (a) that Rochal® Bioshield Silicone Film is substantially equivalent to the predicate device, as it has the same intended uses as the predicate device; and (b) demonstrates the device is at least as safe and effective as the legally marketed predicate device.