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

July 26, 2016

Rochal Industries LLC
Mr. William Coulston
Quality And Regulatory Affairs
12719 Cranes Mill
San Antonio, Texas 78230

Re: K160684
Trade/Device Name: Atteris No-Sting Skin Protectant
Regulation Number: 21 CFR 880.5090
Regulation Name: Liquid bandage
Regulatory Class: Class I
Product Code: KMF
Dated: June 15, 2016
Received: June 21, 2016

Dear Mr. 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. 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" (21 CFR 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)*

K160684

Device Name
Atteris No-Sting Skin Protectant

Indications for Use *(Describe)*

Atteris No Sting Skin Protectant is intended for application to intact or damaged skin as a liquid, film-forming product, which creates a long-lasting waterproof barrier, protecting the skin from bodily wastes, fluids, adhesive products, and friction. It is intended as a primary barrier against irritation from body fluids.

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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Rochal Industries LLC
510(k) Notification
Atteris™ No Sting Skin Protectant

510(k) Summary

510(k) Summary

1. Submitter's Name and Address
Rochal Industries LLC.
12719 Cranes Mill
San Antonio, Texas, 78230

2. Submitter's Contact Person
William J. Coulston
Quality and Regulatory Affairs
(210) 870-6534
wcoulston@rochalindustries.com

3. Date of 510(k) Summary Preparation:
26 July 2016

4. Device Name (Proprietary)
Atteris™ No Sting Skin Protectant

5. Common Name
Skin Protectant

6. Classification Name
Bandage, Liquid

7. Device Class
II

8. Device Code
KMF

9. Legally Marketed Device for substantial equivalence comparison:

Feature Being Compared	PROPOSED DEVICE Atteris No Sting Skin Protectant	PREDICATE DEVICE 3M No Sting Barrier Film

Indications for Use (OTC)	Atteris No Sting Skin Protectant is intended for application to intact or damaged skin as a liquid, film-forming product, which creates a long- lasting waterproof barrier, protecting the skin from bodily wastes, fluids, adhesive products, and friction. It is intended as a primary barrier against irritation from body fluids.	K955103: 3M No Sting Barrier Film also known as Cavilon 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.
Appearance	Clear, colorless solution	Clear, colorless solution

10. Description of Device

Atteris No Sting Skin Protectant is a polymeric solution which forms a uniform film when applied to the skin. The product is biocompatible, non-stinging, and fast drying. Atteris No Sting Skin Protectant shields intact or damaged skin from irritation caused by bodily fluids, wound drainage, adhesives, and friction. The film is colorless, transparent, and possesses good oxygen and moisture vapor permeability.

Atteris No Sting Skin Protectant will be supplied in a High Density Polyethylene (HDPE) bottle with pump spray cap.

Rochal INDUSTRIES LLC

11. Intended Use of Device

Atteris No Sting Skin Protectant is intended for over-the-counter (OTC) use as follows:

- Atteris No Sting Skin Protectant is intended for application to intact or damaged skin as a liquid, film-forming product, which creates a long-lasting waterproof barrier, protecting the skin from bodily wastes, fluids, adhesive products, and friction.

- It is intended as a primary barrier against irritation from body fluids.

These indications are similar to that of the predicate device.

12. Device Technological Characteristics

Atteris No Sting Skin Protectant is a polymeric solution which forms a uniform film when applied to the skin. The product is biocompatible, non-stinging, and fast drying. Atteris No Sting Skin Protectant shields intact or damaged skin from irritation caused by bodily fluids, wound drainage, adhesives, and friction. The film is colorless, transparent, and possesses good oxygen and moisture vapor permeability. Atteris No Sting Skin Protectant is manufactured under Good Manufacturing Practices (GMP) guidelines.

13. Performance Testing

Atteris No Sting Skin Protectant has been subjected to ISO 10993 biocompatibility studies (cytotoxicity, sensitization, irritation) 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 accelerated aging study indicates the product is expected to be stable and effective for a shelf life of 12 months.

The No Sting Skin Protectant has the following characteristics and was tested to confirm the substantiation of these claims. See below:

- No Sting - this claim was supported by human testing using the Skin Trauma After Razor Shaving (STARS) bioassay to determine if NSP caused subjective stinging when applied to skin that had been challenged by dry shaving. NSP is non-stinging.

- Barrier Film - Human testing was conducted at cyberDERM Clinical Studies to determine barrier function using a carbon retention test method. NSP is a barrier film.

- Sterile - Based on USP 71, after 2 month of accelerated aging, the Atteris No Sting Skin Protectant (NSP) passed the requirements for sterility with no observed turbidity in the 10 test samples.

- Breathable - Breathability was assessed by using oxygen and moisture vapor transmission rate testing. NSP is breathable.

- Biocompatible - Testing consistent with ISO 10993 (Cytotoxicity, Sensitization, and Irritation) testing was conducted.

    - Cytotoxicity Study Summary
      L929 Agar Diffusion Test (Direct Contact) - ISO
      Final GLP Report: 15-04007-G1
      Test Article Name: Atteris Skin Protectant
      The potential biological reactivity of a mammalian cell culture (mouse fibroblast L929) in response to exposure to the test article, Atteris Skin Protectant, was determined.

    - Direct Primary Skin Irritation Test - ISO
      Final GLP Report: 15-04007-G2
      Test Article Name: Atteris Skin Protectant
      The test article, Atteris Skin Protectant, was evaluated for its potential to produce Primary Skin Irritation after a single topical minimum 4 hour application to abraded skin sites of New Zealand White rabbits.

    - Direct Buehler Sensitization Test - ISO
      Final GLP Project: 15-04007-G3
      Test Article Name: Atteris Skin Protectant
      The test article, Atteris Skin Protectant, was evaluated for its potential to produce skin sensitization reactions following topical application to albino guinea pigs.

    - NSSP is non-cytotoxic, non-sensitizing, and non-irritating.

- Dries in ~60 seconds - Human testing was conducted at cyberDERM Clinical Studies to determine dry time. NSP dries in approximately 60 seconds.

- Good in Skin Folds (non-self-adherent) - Human testing was conducted at cyberDERM Clinical Studies to determine self-adherence of NSP in comparison to the commercial control, 3M Cavilon No Sting Barrier Film. NSP is consider non-self-adherent.

- Single Patient Use (Use life-28 days after opening) - Use life testing was conducted in which the product was opened, sprayed, and left open. Testing

was conducted after 28-days to confirm the product retains its performance characteristics, and it does. The Use Life is 28 days after opening, after which the product should be discarded.

The previously mentioned testing was conducted to substantiate the claims of the Atteris No Sting Skin Protectant, which is substantially equivalent to the predicate device 3M's Cavilon Barrier Film since the two products have similar claims, intended uses, and formulation.

14. Substantial Equivalence Conclusion

As discussed in this 510(k) submission, Atteris No Sting Skin Protectant is similar in function and has the same intended use as the predicate device, 3M No Sting Barrier Film. The safety evaluation meets the requirements as detailed by USP and ISO.

On the basis of the information presented in this 510(k) submission, Rochal Industries LLC. concludes a) that Atteris No Sting Skin Protectant is substantially equivalent to the predicate device, as it has the same intended use as the predicate; and b) demonstrates the device is as safe and effective as the legally marketed predicate device.