DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 30, 2016

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

Re: K161212
Trade/Device Name: Atteris Antimicrobial Barrier Film Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 22, 2016
Received: April 28, 2016

Dear 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. 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)*

K161212

Device Name

Atteris Antimicrobial Barrier Film Dressing

Indications for Use *(Describe)*

Atteris Antimicrobial Barrier Film Dressing is intended for application to minor wounds and damaged skin as a liquid, film forming barrier, which creates a waterproof, film dressing, protecting the wound or damaged 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.

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510(k) Summary - K161212

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 Affairs

(210) 870-6534
wcoulston@rochalindustries.com

3. **Date of 510(k) Summary Preparation:**
29 September 2016

4. **Device Name (Proprietary)**
Atteris™ Antimicrobial Barrier Film Dressing

5. **Common Name**
Wound Dressing

6. **Classification Name**
Dressing, Wound, Drug

7. **Device Class**
Unclassified

8. **Device Code**
FRO

9. Legally Marketed Device for substantial equivalence comparison:

	Proposed: Atteris Antimicrobial Barrier Film Dressing	**Predicate:** Kendall COPA AMD	**Reference:** Poly FIT +Absorbing Antimicrobial Dressing	**Reference:** ASAP OTC™ Wound Dressing Gel	**Reference:** Prontosan™ Gel X
K Number	New	K071371	K 121522	K140483	K130857
Class	Unclassified	Unclassified	Unclassified	Unclassified	Unclassified
Regulation	Unknown	Unknown	Unknown	Unknown	Unknown
Device Classification Name	Dressing, Wound, Drug	Dressing, Wound, Drug	Dressing, Wound, Drug	Dressing, Wound, Drug	Dressing, Wound, Drug
Product Code	FRO	FRO	FRO	FRO	FRO

Intended use	Atteris Antimicrobial Barrier Film Dressing is a polymeric solution which forms a uniform film when applied to minor wounds and damaged skin.	COPA AMD dressings are indicated for use in management of post-surgical incisions, pressure sores, venous stasis ulcers, diabetic ulcers, donor sites, abrasions, lacerations, 1st and 2nd degree burns, dermatologic disorders, other wounds inflicted by trauma and, as a secondary dressing or cover dressing for packed wounds.	For Over-the-Counter Use, PolyFITM+ Absorbing Antimicrobial Dressings may be used for minor abrasions, minor lacerations, minor cuts, minor scalds, and minor burns.	ASAP OTC Wound Dressing is indicated for the topical management of minor cuts, 1st and 2nd degree burns, and skin irritations.	Prontosan Wound Gel X is a ready to use, clear, odorless, amorphous hydrogel wound dressing that helps maintain a clean, moist wound environment. It is intended as a barrier to resist microbial colonization within the dressing and reduce microbial penetration through the dressing.
Indications for use	Atteris Antimicrobial Barrier Film Dressing is intended for application to minor wounds and damaged skin as a liquid, film forming barrier, which creates a waterproof, film dressing, protecting the wound or damaged skin.	Same as above.	Same as above	Same as above	OTC - Prontosan Wound Gel X is indicated for the management of minor cuts. minor lacerations, minor burns (1st degree burns), and abrasions.
Rx or OTC use	OTC	Rx	OTC	OTC	OTC

Design	Atteris™ Antimicrobial Barrier Film Dressing is a polymeric solution which forms a uniform film when applied to minor wounds and damaged skin. The product is dispersed in a unique non-cytotoxic, non-stinging solution via a standard 28 mL pump spray bottle. The product is biocompatible, non-stinging, fast drying, and has low friction. Antimicrobial Barrier Film Dressing protects minor wounds and damaged skin by providing a secure, breathable, waterproof barrier to external contaminates. The film dressing is colorless, transparent, and possesses good oxygen and moisture vapor permeability. The antimicrobial PHMB at a concentration of 0.001% w/w is added to the product as a preservative to inhibit the growth of microorganisms within the product.	A hydrophilic polyurethane foam that is impregnated with Polyhexamethylene Biguanide Hydrochloride (PHMB), an antimicrobial agent that protects the dressing from bacterial penetration and colonization.	PolyFIT+ Absorbing Antimicrobial Dressings are made of synthetic, hydrophilic, fibers embedded with a 0.3% concentration of Polyhexamethylene Biguanide (PHMB).	ASAP OTC Wound Dressing is a water based gel wound dressing that contains silver hydrosol that may inhibit the growth of microorganisms within the dressing. The high moisture content gel contains a base matrix composed of hydrophilic and buffering compounds and contains silver from American Biotech Labs' proprietary silver hydrosol suspension. ASAP OTC Wound Dressing is supplied in a multi-dose gel pump and a tube (collapsible, low-density polyethylene lined metal tube, sealed on one end and fitted with a pop open screw cap on the other end).	Prontosan Wound Gel X is a ready to use, clear, odorless, amorphous hydrogel wound dressing that helps maintain a clean, moist wound environment. The gel matrix includes the preservative, polyhexanide, a viscosity modifying agent and a betaine surfactant. Gel X is supplied sterile in blind ended, heat sealed polyfoil 250g tubes fined with PP screw caps.

Performance	Performance data submitted in support of this 510k included in-vitro testing. As a preservative, broad spectrum activity was demonstrated against 5 organisms including Gram positive, Gram negative, and fungal types. Total kill was achieved for 24 hours at >6 log of each organism: • *P. aeruginosa* • *E. coli* • *C. albicans* • *S. aureus* • *A. brasiliensis*	Performance data submitted in support of this 510k included in-vitro and animal testing. Broad spectrum activity was demonstrated against 6 organisms including Gram positive, Gram negative, and fungal types. Total kill was achieved for 7 consecutive days, with a daily challenge of >6 log of each organism: • *P. aeruginosa* • *E. coli* • *C. albicans* • *S. epidermidis* • *S. aureus* • *E. faecalis*	All necessary verification and validation testing has been performed for the PolyFIT+ Absorbing Antimicrobial Dressings to assure substantial equivalence to the predicate devices.	Performance data submitted in support of this 510k included in-vitro and animal testing.	Biocompatibility and performance testing was performed with Prontosan Wound Gel X to support substantial equivalence to the predicate devices. Biocompatibility testing was performed in accordance with ISO 10993-1. Performance testing completed included USP<51 > and a Strike Through Barrier Test. Test results met the acceptance criteria.

Materials	Acrylate copolymer Hexamethyldisiloxane 2,2,4-Trimethylpentane Water Docusate sodium Polyhexamethylene biguanide (PHMB)	Polyurethane foam Polyhexamethylene biguanide (PHMB)	Polyethylene oxide (PEO) Polyethylene-co-vinyl-alcohol (EVOH) Polycaprolactone (PCL) Polyhexamethylene biguanide (PHMB)	Carbopol ETD 2020 Water Triethanolamine (TEA) ASAP Solution	Hydroxyethylcellulos e Glycerol Water Betaine surfactant Polyhexanide (PHMB)
Bio-compatibility	ISO 10993 parts 1,5, and 10	ISO 10993 parts 1, 5, 10	All necessary verification and validation testing has been performed for the PolyFIT+ Absorbing Antimicrobial Dressings	ISO 10993 parts 1, 5, 10	ISO 10993 parts 1, 5, 10
Sterility	Non-sterile product that is preserved using PHMB.	Sterilized using ETO later changed to gamma irradiation (see K082296).	Sterile	Non-sterile	Sterile using steam sterilization

10. Description of Device

Atteris™ Antimicrobial Barrier Film Dressing is a polymeric solution which forms a uniform film when applied to minor wounds and damaged skin. The product is biocompatible, non-stinging, and fast drying.

The barrier film is colorless, transparent, and possesses good oxygen and moisture vapor permeability. Atteris Antimicrobial Barrier Film Dressing will be supplied in a High Density Polyethylene (HDPE) bottle with pump spray cap.

11. Indications For Use of Device

Atteris Antimicrobial Barrier Film Dressing is intended for over-the-counter (OTC) use as follows:

Atteris Antimicrobial Barrier Film Dressing is intended for application to minor wounds and damaged skin as a liquid, film forming barrier, which creates a waterproof, film dressing, protecting the wound or damaged skin.

These indications are similar to that of the predicate device and reference devices.

12. Device Technological Characteristics

Atteris Antimicrobial Barrier Film Dressing is a polymeric solution which forms a uniform film when applied to the skin. The product is biocompatible, non-stinging, and fast drying. The film is colorless, transparent, and possesses good oxygen and moisture vapor permeability. Atteris Antimicrobial Barrier Film Dressing is manufactured under Good Manufacturing Practices (GMP) guidelines.

13. Performance Testing

Atteris Antimicrobial Barrier Film Dressing (ABF) 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 preserved and preservative effectiveness has been verified using USP 51. The results of real-time aging studies indicates the product is expected to be stable and effective for a shelf life of 6 months.

The Antimicrobial Barrier Film Dressing (ABF) has the following characteristics and was tested to confirm the substantiation of these claims. See below:

- Preserved - Based on USP 51 initially and at several points during aging.
- Biocompatible - Testing consistent with ISO 10993 (Cytotoxicity, Sensitization, and Irritation) testing was conducted. ABF is non-cytotoxic, non-sensitizing, and non-irritating.

- Other performance characteristics.

The previously mentioned testing was conducted to substantiate the claims of the Atteris Antimicrobial Barrier Film Dressing, which is substantially equivalent to the predicate device Kendall COPA AMD since the two products have similar claims and intended uses.

14. Substantial Equivalence Conclusion

As discussed in this 510(k) submission, Atteris Antimicrobial Barrier Film Dressing is similar in function and has the same intended use as the predicate device, Kendall COPA AMD (K071371). 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 Antimicrobial Barrier Film Dressing is substantially equivalent to the predicate device, as it has the same intended use for minor wounds as the predicate; and b) demonstrates the device is as safe and effective as the legally marketed predicate device.