DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 28, 2016

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

Re: K160192
Trade/Device Name: Atteris Antimicrobial Skin & Wound Cleanser
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 22, 2016
Received: June 28, 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,

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)*

K160192

Device Name
Atteris Antimicrobial Skin & Wound Cleanser

Indications for Use *(Describe)*

(Rx Only) Atteris Antimicrobial Skin & Wound Cleanser is intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites.

(OTC use) Atteris Antimicrobial Skin & Wound Cleanser is intended for physical cleaning and removal of dirt and debris, from skin scrapes, cuts, lacerations, minor irritations, exit sites and unbroken 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.

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Rochal Industries LLC
510(k) Notification
Atteris™ Antimicrobial Skin and Wound Cleanser

SECTION 5

510(k) Summary

Section 5: 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™ Antimicrobial Skin & Wound Cleanser

5. **Common Name**
   Skin and Wound Cleanser

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

7. **Device Class**
   Unclassified

8. **Device Code**
   FRO

9. **Comparison of Features**

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Feature Being Compared	PROPOSED DEVICE Atteris Antimicrobial Skin & Wound Cleanser	PREDICATE DEVICE Anasept Antimicrobial Skin and Wound Cleanser (K073547)	REFERENCE DEVICE NAWAlution Skin and Wound Cleanser (K141660)
Biocompatibility	Biocompatible	Biocompatible	Biocompatible
Appearance	Clear, colorless solution	Clear, colorless liquid	Clear, colorless solution
Application method	Spray bottle (8 fluid oz) with trigger sprayer.	15 oz in HDPE bottle with dispensing caps and 8, & 12 oz with Trigger sprayer and 8 oz with Finger pump sprayer.	Spray bottle (50 mL (1.8 fluid oz.) – OTC); Spray bottle (8 fluid oz. (237 mL) or 16 fluid oz. (473 mL) – Rx)
Characteristics	Aqueous	Aqueous	Aqueous
Density	~ 1.0 g/ml	~1.0 g/ml	0.9 – 1 g/ml
Materials	Purified Water, Poloxamer 407, Sodium Chloride, Ethylhexylglycerin, Hypromellose, Octane-1,2-diol, Polyaminopropyl Biguanide [PHMB],	Purified water, Sodium Chloride, Sodium Hypochlorite	Purified water, Cocamidopropylbetaine, Zinc Chloride, PHMB, Hydrochloric acid, Trace Element
Buffer	Not buffered	Not buffered	Not buffered
Sterility	Non-sterile	Non-sterile	Non-sterile

10. Description of Device

Atteris Antimicrobial Skin & Wound Cleanser helps in the mechanical removal of debris and foreign material from the skin, wound or application site. Atteris Antimicrobial Skin & Wound Cleanser is a pure, colorless, isotonic cleanser that is safe. The cleanser has a six month expiration due to the preservative that provides bactericidal and fungicidal properties through the action of the antimicrobial (PHMB).

A preservative, PHMB, at a concentration of 0.1% w/w is added to the product to inhibit the growth of microorganisms such as, *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, *Escherichia coli*, antibiotic resistant Methicillin Resistant *Staphylococcus aureus* (MRSA), and fungus *Candida albicans* within the product.

11. Intended Use of Device

Atteris Antimicrobial Skin & Wound Cleanser is intended for over-the-counter (OTC) and professional use as follows:

a. For Over-the-Counter Use: Atteris Antimicrobial Skin & Wound Cleanser is

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intended for physical cleaning and removal of dirt and debris, from skin scrapes, cuts, lacerations, minor irritations, exit sites and unbroken skin.

b. Professional Use: (Rx Only) Atteris Antimicrobial Skin & Wound Cleanser is intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds such as stage I-IV pressure ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites.

12. Device Technological Characteristics

a. Atteris Antimicrobial Skin & Wound Cleanser is a clear isotonic solution to aid in the mechanical removal of debris and foreign material from the application site. This is accomplished through the flow of the solution moving across the application site with or without the assistance of a suitable wound dressing. Atteris Antimicrobial Skin & Wound Cleanser solution contains PHMB that inhibits the growth of microorganisms within the solution. The Atteris Antimicrobial Skin and Wound Cleanser is similar in form, fit, and function to the primary predicate device, which is legally marketed. The ingredients more closely match the reference device, NAWAlution however, the primary component in all devices is purified water, as shown above. The main ingredient is water. Sodium chloride and EDTA are added to the formulation to match the osmolality and pH to that of healthy tissue. Hypromellose is added to increase the viscosity of the fluid. Sensivas (2-Ethylhexylglycerin and 2-ethylhexylglycerin and 1,2-octanediol) were added as moisturizers. Poloxamer 407 was used as a surfactant to incorporate Sensivas into the formulation. Finally, PHMB was used as a preservative.

b. Anasept Antimicrobial Skin and Wound Cleanser uses sodium hypochlorite as a preservative. This is a buffered solution and at this concentration (0.057%) [1] is non-cytotoxic [2]. It is non-irritating and non-sensitizing [1]. Anasept Antimicrobial Skin and Wound Cleanser is a modified Dakin's solution, which has been used for over 100 years to disinfect wounds [2]. Although Atteris Antimicrobial Skin and Wound Cleanser (AWC) uses a different preservative (PHMB) to protect the contents of the bottle, it is also a buffered solution [3] is non-cytotoxic [4]. It is also non-irritating [5] and non-sensitizing [6]. PHMB has been used for decades in a wide range of applications including as a preservative in cosmetics and contact lens solutions and as a swimming pool sanitizer [7].

The similarities and differences of the preservatives are summarized in **Figure 1.**

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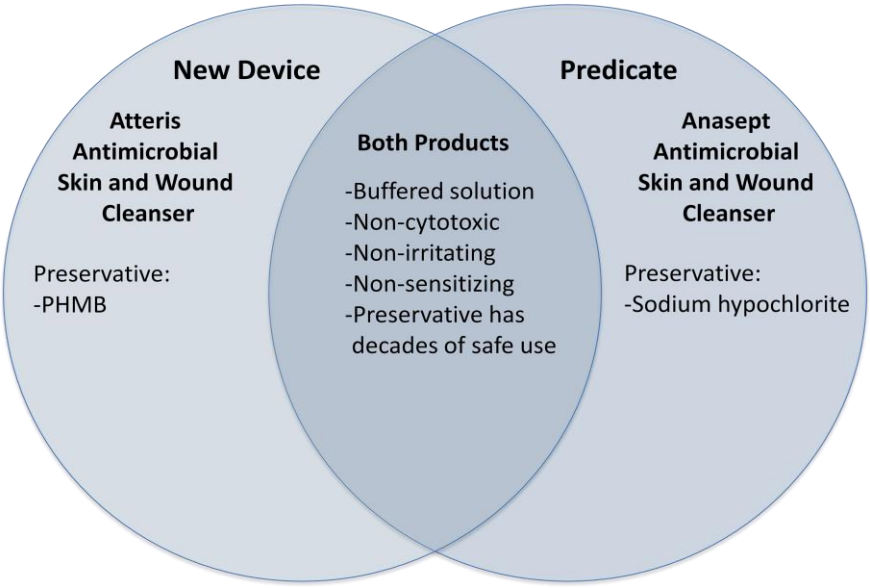
Figure 1: Similarities Between Anasept and Atteris Wound Cleansers



In summary, both Anasept and Atteris Antimicrobial Skin and Wound Cleanser (AWC) are buffered solutions with preservatives to protect the solution from contaminants. Both preservatives (PHMB and sodium hypochlorite) have a long history of use.

13. Performance Testing

Atteris Antimicrobial Skin & Wound Cleanser has been subjected to ISO 10993 biocompatibility studies (cytotoxicity, sensitization, irritation) to demonstrate that the device is as safe and as effective as its predicate devices. The preservative effectiveness has been supported by USP <51> testing. Additionally, test results have demonstrated preservative effectiveness against the following five microorganisms, Escherichia coli (ATCC No. 8739), Staphylococcus aureus (ATCC No. 6538), Pseudomonas aeruginosa (ATCC No. 27853), Staphylococcus epidermidis (ATCC No. 12228) and Candida albicans (ATCC No. 10231). The results of real-time aging study indicates the product is expected to be stable and effective for a shelf life of 6 months.

14. Substantial Equivalence Conclusion

As discussed in this 510(k) submission, Atteris Antimicrobial Skin & Wound Cleanser is similar in function and has the same intended use as the predicate device, Anasept Antimicrobial Skin and Wound Cleanser. 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 Skin & Wound Cleanser 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.

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References:

1. Anacapa, Safety Data Sheet- Anasept Antimicrobial Skin and Wound Gel. 2015.
2. Levine, J.M., Dakin's solution: past, present, and future. Adv Skin Wound Care, 2013. 26(9): p. 410-4.
3. Rochal, Atteris Antimicrobial Skin and Wound Cleanser Product Insert. 2016.
4. Toxikon, Rochal Wound Cleanser Final GLP Report - 15-03643-G1 : L929 Agar Diffusion Test (Direct Contact) - ISO. 2015.
5. Toxikon, Rochal Wound Cleanser Final GLP Report - 15-03643-G2 : Direct Primary Skin Irritation Test - ISO. 2015.
6. Toxikon, Rochal Wound Cleanser Final GLP Report - 15-03643-G4 : Direct Buehler Sensitization Test - ISO. 2015.
7. Butcher, M., PHMB: an effective antimicrobial in wound bioburden management. Br J Nurs, 2012. 21(12): p. S16, S18-21.
8. Anacapa, Anasept Antimicrobial Skin and Wound Care Products Brochure. 2015.
9. Estrela, C., et al., Mechanism of action of sodium hypochlorite. Braz Dent J, 2002. 13(2): p. 113-7.
10. Lineaweaver, W., et al., Topical antimicrobial toxicity. Arch Surg, 1985. 120(3): p. 267-70.
11. Moore K, G.D., Using PHMB antimicrobial to prevent wound infection. Wounds UK, 2007. 3(2): p. 96-102.