May 28, 2021

Irrimax Corporation
Christy Coleman
VP Regulatory
1665 Lakes Parkway, Suite 102
Lawrenceville, Georgia 30043

Re: K210536
Trade/Device Name: Irrisept Antimicrobial Wound Lavage
Regulatory Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II, unclassified
Product Code: FQH, FRO
Dated: February 19, 2021
Received: February 24, 2021

Dear Christy Coleman:

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,

Lixin Liu, Ph.D.
Assistant Director (Acting)
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210536

Device Name

Irrisept® Antimicrobial Wound Lavage

Indications for Use *(Describe)*

Irrisept® Antimicrobial Wound Lavage is intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds.

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

PREPARATION DATE:	27 May 2021
510(K) NUMBER:	K210536
APPLICANT:	Irrimax® Corporation 1665 Lakes Parkway, Suite 102 Lawrenceville, GA 30043
CONTACT PERSON:	Christy Coleman, OD, MPH Vice President, Regulatory Affairs, Irrimax® Corporation Tel: (770) 807-3355
DEVICE TRADE NAME:	Irrisept® Antimicrobial Wound Lavage
CLASSIFICATION NAME:	Jet Lavage
DEVICE CLASSIFICATION:	Class II (21 CFR 880.5475) Unclassified (Pre-amendment)
PRODUCT CODE:	FQH; FRO
PRIMARY PREDICATE DEVICE:	Irrisept® Wound Debridement and Cleansing System Product Code: FQH (Jet Lavage); Class II (21 CFR 880.5475) Product Code FRO (Dressing, Wound, Drug); Unclassified (pre-amendment) Applicant: Irrimax Corporation *Cleared under K202222 on December 14, 2020*
SECONDARY PREDICATE DEVICE:	Atteris Antimicrobial Skin and Wound Cleanser Product Code: FRO (Dressing, Wound, Drug); Unclassified (pre-amendment) Applicant: Rochal Industries, LLC *Cleared under K160192 on July 28, 2016*

DEVICE DESCRIPTION:

Irrisept® Antimicrobial Wound Lavage is a single-use, manual, self-contained irrigation device comprised of a 450mL bottle of 0.05% Chlorhexidine Gluconate (CHG) in 99.95% Sterile Water for Irrigation, United States Pharmacopeia (USP) and an applicator (labeled Irriprobe®). The solution is aseptically-filled in a Blow-Fill-Seal (BFS) bottle. The CHG acts as a preservative to inhibit microbial growth in the solution.

INTENDED USE/INDICATIONS FOR USE:
Irrisept® Antimicrobial Wound Lavage is intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:
The Irrisept device that is the subject of this 510(k) is substantially equivalent to its predicate, predecessor K202222, Irrisept. The Irrisept solution contains 0.05% Chlorhexidine Gluconate (CHG) in 99.95% Sterile Water for Irrigation that acts as a preservative to inhibit microbial growth in the solution. The Irrisept Antimicrobial Wound Lavage is unchanged from the legally marketed predicate Irrisept device (K202222) in its intended use, performance, and technological characteristics. The removal of wound debris, including dirt, foreign materials and microorganisms, is consistent with the secondary predicate device (Atteris Antimicrobial Skin & Wound Cleanser, legally marketed under K160192). Both devices have the same intended use and apply a solution to the wound for removal of wound debris. This 510(k) is to specify the removal of microorganisms through mechanical cleansing action within the indications for use statement of the Irrisept® device, consistent with the Atteris predicate device.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS			
Comparison Feature	**PROPOSED DEVICE** **Irrisept Antimicrobial Wound Lavage**	**PREDICATE DEVICE** **Irrisept Wound Debridement and Cleansing System**	**SECONDARY PREDICATE DEVICE** **Atteris Antimicrobial Skin & Wound Cleanser**
510(k) Number	K210536	K202222	K160192
Product Code	FQH, Jet Lavage FRO, Dressing, Wound, Drug	FQH, Jet Lavage FRO, Dressing, Wound, Drug	FRO, Dressing, Wound, Drug
Product Classification	Class II (21 CFR 880.5475) Unclassified (Pre-amendment)	Class II (21 CFR 880.5475) Unclassified (Pre-amendment)	Unclassified (Pre-amendment)
Intended Use	Intended for wound cleansing and removal of wound debris	Intended for wound cleansing and removal of wound debris	Intended for wound cleansing and removal of wound debris
Indications for Use	Irrisept® Antimicrobial Wound Lavage is intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds.	Irrisept Wound Debridement and Cleansing System is a wound cleansing and delivery system. The mechanical action effectively loosens and removes wound debris.	(Rx use) 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	Prescription use only	Prescription use only	Both prescription use and over-the-counter use
Mechanism of Action	The mechanical action of fluid across the wound removes wound debris.	The mechanical action of fluid across the wound removes wound debris.	The mechanical action of fluid across the wound removes wound debris.
Solution	0.05% Chlorhexidine Gluconate in 99.95% Sterile Water for Irrigation, USP	0.05% Chlorhexidine Gluconate in 99.95% Sterile Water for Irrigation, USP	Purified Water, Poloxamer 407, Sodium Chloride, Ethylhexylglycerin, Hypromellose, Octane-1,2-diol, Polyaminopropyl Biguanide [PHMB]
Solution Antimicrobial Preservative	Chlorhexidine Gluconate	Chlorhexidine Gluconate	Polyaminopropyl Biguanide [PHMB]
How Supplied	Provided for single use. A 450 mL bottle of Irrisept is double wrapped in CSR and sealed within an outer Tyvek® pouch. The bottle exterior, CSR wraps, and applicator are sterilized by EO. The bottle contains aseptically processed Irrisept solution.	Provided for single use. A 450 mL bottle of Irrisept is double wrapped in CSR and sealed within an outer Tyvek® pouch. The bottle exterior, CSR wraps, and applicator are sterilized by EO. The bottle contains aseptically processed Irrisept solution.	Provided non-sterile in 8 fluid ounce bottle with sprayer.
Applicator	Multiport applicator that threads onto the Irrisept Bottle	Multiport applicator that threads onto the Irrisept Bottle	Sprayer attachment

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS			
Comparison Feature	**PROPOSED DEVICE** **Irrisept Antimicrobial Wound Lavage**	**PREDICATE DEVICE** **Irrisept Wound Debridement and Cleansing System**	**SECONDARY PREDICATE DEVICE** **Atteris Antimicrobial Skin & Wound Cleanser**
Sterilization	Bottle exterior, CSR wraps, and outer packaging conforms to ISO 11135-7 for EO sterilization and ISO 10993-7 for EO residuals whereas the solution is aseptically processed	Bottle exterior, CSR wraps, and outer packaging conforms to ISO 11135-7 for EO sterilization and ISO 10993-7 for EO residuals whereas the solution is aseptically processed	Provided non-sterile
Biocompatibility	Biocompatible per ISO 10993 testing for a surface device with breached or compromised surface contact and a limited duration (≤ 24 hours)	Biocompatible per ISO 10993 testing for a surface device with breached or compromised surface contact and a limited duration (≤ 24 hours)	Biocompatible per ISO 10993 testing
Preservative Effectiveness over Shelf-Life	Demonstrated per USP <51> testing	Demonstrated per USP <51> testing	Demonstrated per USP <51> testing

There are no technological differences between the two versions of Irrisept. The change to the Irrisept labeled indication for use to include removal of "microorganisms" as a type of wound debris does not change the intended use of the device and does not raise new safety and effectiveness concerns. Substantial equivalence has been confirmed through performance testing.

PERFORMANCE TESTING:
Performance testing is unchanged between Irrisept Antimicrobial Wound Lavage and the predicate Irrisept device for biocompatibility, aseptic processing, sterility, preservative antimicrobial effectiveness, endotoxin and pyrogen testing, EO sterilization, packaging integrity, and shelf-life validation. Performance testing demonstrates that the subject Irrisept is as safe and as effective as the predicate, predecessor Irrisept product. These tests include:

- Preservative Antimicrobial Effectiveness
  - USP <51> Antimicrobial Effectiveness Testing
- Aseptic Processing
  - ISO 13408 - Aseptic Processing of Health Care Products
- Sterilization
  - ISO 11135 - Sterilization of Health-Care Products - Ethylene Oxide
  - ANSI AAMI ISO 10993-7 - Ethylene oxide sterilization residuals
  - USP <71> Sterility Tests
  - AAMI TIR 28 - Product adoption and process equivalence for ethylene oxide sterilization
- Endotoxins and Pyrogens
  - USP <85> Bacterial Endotoxins Test
  - USP <151> Pyrogen Test (USP Rabbit Test)
  - USP <161> Medical Devices- Bacterial Endotoxin and Pyrogen Tests
- Packaging and Shelf-Life
  - ISO 11607 - Packaging for Terminally Sterilized Medical Devices
  - ASTM F1980-16 - Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
  - ASTM F2096-11 - Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
  - ASTM F1929-15 - Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration
  - ASTM D4169-16 - Standard Practice for Performance Testing of Shipping Containers and Systems
- Biocompatibility
  - ISO 10993- Biological Evaluation of Medical Devices

In addition, the subject device was also tested to show mechanical action equivalent to the predicate devices, demonstrating that the fluid dispensed during the use of the device is sufficient to mechanically remove debris, including microorganisms, from wounds.

SUBSTANTIAL EQUIVALENCE CONCLUSION:

The performance testing conducted demonstrates that the Irrisept Antimicrobial Wound Lavage is substantially equivalent to the predicate Irrisept device in intended use and technological characteristics and this premarket notification supports the addition of "microorganisms" as a type of wound debris removed by the device in the labeled indications for use.