September 22, 2022

Irrimax Corporation
Tanya Eberle
VP Regulatory Affairs
1665 Lakes Parkway, Suite 102
Lawrenceville, Georgia 30043

Re: K222804
Trade/Device Name: Irrisept® Antimicrobial Wound Lavage
Regulatory Class: Unclassified
Product Code: FRO, FQH
Dated: September 15, 2022
Received: September 16, 2022

Dear Tanya Eberle:

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,

Julie Morabito, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K222804

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

SUBMITTER'S INFORMATION

Owner:	Irrimax® Corporation
Address:	1665 Lakes Parkway, Suite 102, Lawrenceville, GA 30043
Phone:	770-807-3355
Contact Person:	Tanya Eberle, VP, Regulatory Affairs
Date Summary Prepared:	September 15, 2022

DEVICE INFORMATION

Name of Device:	Irrisept® Antimicrobial Wound Lavage
Classification Name:	Jet Lavage
Product Code:	FQH; FRO
Predicate Device:	Irrisept® Antimicrobial Wound Lavage Product Code: FQH (Jet Lavage); Class II (21 CFR 880.5475) Product Code: FRO (Dressing, Wound, Drug); Unclassified (pre-amendment) cleared under K210536
Device Description:	Irrisept® Antimicrobial Wound Lavage is a single-use, manual, self-contained irrigation device comprised of a bottle of 0.05% Chlorhexidine Gluconate (CHG) in 99.95% Sterile Water for Irrigation, United States Pharmacopeia (USP) and accessories for irrigation. 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 the Technological Characteristics:	The 150 mL and 450 mL Irrisept® Antimicrobial Wound Lavage devices provide the same aseptically-filled solution of 0.05% Chlorhexidine Gluconate (CHG) in 99.95% Sterile Water for Irrigation, United States Pharmacopeia (USP) in a Blow-Fill-Seal bottle. The 150 mL Irrisept® Antimicrobial Wound Lavage device is provided in a non-sterile packaged configuration where the 450 mL Irrisept® Antimicrobial Wound Lavage device is sterile packaged. The 150 mL Irrisept® Antimicrobial Wound Lavage device includes a solution-filled bottle with integrated applicator where the 450 mL Irrisept® Antimicrobial Wound Lavage device includes a separate sterile applicator that is threaded onto the solution-filled bottle at the time of use. All safety and technological aspects of mechanical cleansing and removal of wound debris are preserved. The Irrisept® Antimicrobial Wound Lavage device use and performance characteristics are not altered by this modification.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS		
Comparison Feature	**CLEARED IRRISEPT DEVICE Irrisept® Antimicrobial Wound Lavage (450 ml)**	**SUBJECT IRRISEPT DEVICE Irrisept® Antimicrobial Wound Lavage (150 ml)**
510(k) Number	K210536	K222804
Product Code	FQH, Jet Lavage FRO, Dressing, Wound, Drug	FQH, Jet Lavage FRO, Dressing, Wound, Drug
Product Classification	Class II (21 CFR 880.5474) Unclassified (Pre-amendment)	Class II (21 CFR 880.5474) Unclassified (Pre-amendment)
Intended Use	Intended for wound cleansing and removal of wound debris	Identical
Indications for Use	Irrisept Antimicrobial Wound Lavage intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds.	Identical
Type of Use	Prescription Use Only	Identical
Mechanism of Action	The mechanical action of fluid across the wound removes wound debris.	Identical
Solution	0.05% Chlorhexidine Gluconate in 99.95% Sterile Water for Irrigation, USP	Identical
Solution Antimicrobial Preservative	Chlorhexidine Gluconate	Identical
Total Volume	450 mL	150 mL
How Supplied	Provided for single use Bottle of Irrisept and applicator are double wrapped in CSR wrap and sealed within an outer Tyvek® pouch. The bottle contains aseptically processed Irrisept solution.	Provided for single use Bottle of Irrisept with integrated applicator provided within a shelf box. The bottle contains aseptically processed Irrisept solution.
Sterilization	The bottle exterior, CSR wraps, and applicator are sterilized by EO and conform to ISO 11135-7 for EO sterilization and ISO 10993-7 for EO residuals	The bottle exterior and optional splash accessory are non-sterile.
Biocompatibility	Biocompatible per ISO 10993 Testing	Identical
Preservative Effectiveness over Shelf-Life	Demonstrated per USP <51> testing	Identical

Performance Data:

Testing of the 150 mL non-sterile packaged Irrisept® Antimicrobial Wound Lavage was completed, including:

Biocompatibility

- ISO 10993-1 Biological Evaluation of Medical Devices

Aseptic Processing

- ISO 13408 Aseptic Processing of Health Care Products

Preservative Antimicrobial Effectiveness

- USP <51> Antimicrobial Effectiveness

Endotoxins and Pyrogens

- USP <85> Bacterial Endotoxins Test
- USP <151> Pyrogen Test (USP Rabbit Test)
- USP <161> Medical Devices- Bacterial Endotoxin and Pyrogen Tests

Shelf-Life

- USP <51> Antimicrobial Effectiveness
- Sterility USP <71> and chemistry

Functional Testing

- The subject device was assessed for performance through custom tests designed to show the mechanical removal of wound debris, including microorganisms, is equivalent to the predicate device.

Distribution

- ASTM D4169-22 - Standard Practice for Performance Testing of Shipping Containers and Systems

Rationale for Substantial Equivalence:

This modification falls within the FDA regulations for Special 510(k) review. The indication for use, intended use, principles of operation, and performance have not been altered. The minor change to add the new size to the existing Irrisept® Antimicrobial Wound Lavage (150 mL) in a non-sterile packaged configuration does not raise any new questions of safety or effectiveness. The 150 mL Irrisept® Antimicrobial Wound Lavage device has demonstrated the same level of performance as the predicate device (Irrisept® Antimicrobial Wound Lavage, K210536). Therefore, the 150 mL Irrisept® Antimicrobial Wound Lavage device is substantially equivalent to the predicate Irrisept® Antimicrobial Wound Lavage device.

Conclusion:

The Irrisept® Antimicrobial Wound Lavage device, as modified by this 510(k) does not raise any new issues regarding safety or effectiveness. The 150 mL non-sterile packaged Irrisept® Antimicrobial Wound Lavage is suitable for commercial sale and is substantially equivalent to the predicate Irrisept® Antimicrobial Wound Lavage device.