June 18, 2024

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

Re: K240552
Trade/Device Name: Irrisept Antimicrobial Wound Lavage
Regulatory Class: Unclassified
Product Code: FRO
Dated: February 27, 2024
Received: February 28, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Yu-chieh Chiu -S

Yu-Chieh Chiu, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240552

Device Name
Irrisept® Antimicrobial Wound Lavage, Wound Solution Kit

Indications for Use *(Describe)*
Irrisept® Antimicrobial Wound Lavage, Wound Solution Kit 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.

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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: February 28, 2022

DEVICE INFORMATION

Name of Device: Irrisept® Antimicrobial Wound Lavage, Wound Solution Kit

Regulatory Class: Unclassified

Product Code: FRO; FQH

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, self-contained irrigation device comprised of a 450 mL 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, Wound Solution Kit is intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms, from wounds.

Technological Characteristics: This line extension will provide users with the same 450 mL bottle of Irrisept in a shelf box with sterile pouched accessories (spikeable cap and hangers) to facilitate fluid delivery. The Irrisept® Antimicrobial Wound Lavage, Wound Solution Kit configuration does not raise new safety or effectiveness questions. All technological aspects of mechanical cleansing and removal of wound debris are preserved.

Comparison to Predicate: The Irrisept device use and performance characteristics are not altered by this modification.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS		
Comparison Feature	**PREDICATE DEVICE Irrisept® Antimicrobial Wound Lavage (450 ml)**	**SUBJECT DEVICE Irrisept® Antimicrobial Wound Lavage, Wound Solution Kit (450 ml)**
510(k) Number	K210536	K240552
Product Code	FQH, Jet Lavage FRO, Dressing, Wound, Drug	FRO, Dressing, Wound, Drug FQH, Jet Lavage

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS		
Comparison Feature	**PREDICATE DEVICE** **Irrisept® Antimicrobial Wound Lavage (450 ml)**	**SUBJECT DEVICE** **Irrisept® Antimicrobial Wound Lavage, Wound Solution Kit (450 ml)**
Product Classification	Class II (21 CFR 880.5475) Unclassified (Pre-Amendment)	Class II (21 CFR 880.5475) Unclassified (Pre-Amendment)
Intended Use	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 intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds.	Irrisept® Antimicrobial Wound Lavage intended for mechanical cleansing and removal of debris, dirt and foreign materials, including microorganisms from wounds.
Type of Use	Prescription Use Only	Prescription Use Only
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 the irrigation can be by manual or powered irrigation.
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
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 and pouched accessories (spikeable cap and hangers) contained within an outer shelf box. The pouched accessories are sterilized by EO. 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 is non-sterile and the accessories are sterilized by EO and conform to ISO 11135-7 for EO sterilization and ISO 10993-7 for EO residuals
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)
Preservative Effectiveness over Shelf-Life	Demonstrated per USP <51> testing	Demonstrated per USP <51> testing

Performance Data: Testing of the 450 mL non-sterile packaged Irrisept device with accessories was completed, including:

Biocompatibility

- ISO 10993-1 Biological Evaluation of Medical Devices

Aseptic Processing

- ISO 13408 Aseptic Processing of Health Care Products (leveraged from Predicate K210536)

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 (leveraged from Predicate K210536)

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

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

Functional Testing

- ISO 1135-4 Transfusion Equipment for Medical Use
- 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:

The indication for use, intended use, principles of operation, and performance have not been altered. The minor change to add the existing Irrisept device (450 mL) with sterile accessories for use with powered irrigation does not raise any new or different questions of safety or effectiveness. The Irrisept device under this Traditional 510(k) has demonstrated the same level of performance as the predicate device (Irrisept, K210536) and is therefore substantially equivalent.

Conclusion:

The Irrisept® Antimicrobial Wound Lavage, Wound Solution Kit device, as modified by this 510(k) does not raise any new issues regarding safety or effectiveness. The Irrisept Wound Solution Kit (450 mL Irrisept solution and sterile-pouched accessories) is suitable for commercial sale and is substantially equivalent to the predicate Irrisept® Antimicrobial Wound Lavage device.