December 14, 2020

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

Re: K202222
Trade/Device Name: Irrisept Wound Debridement and Cleansing System
Regulation Number: 21 CFR 880.5475
Regulation Name: Jet Lavage
Regulatory Class: Class II, unclassified
Product Code: FQH, FRO
Dated: November 12, 2020
Received: November 13, 2020

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,

For Kimberly Ferlin, 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)*
K202222

Device Name

Irrisept Wound Debridement and Cleansing System

Indications for Use *(Describe)*

The Irrisept Wound Debridement and Cleansing System is a wound cleansing delivery system. The mechanical action effectively loosens and removes wound debris.

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

510(K) NUMBER:	K202222
PREPARATION DATE:	December 11, 2020
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® Wound Debridement and Cleansing System
CLASSIFICATION NAME:	Jet Lavage
DEVICE CLASSIFICATION:	Class II (21 CFR 880.5475) Unclassified (Pre-amendment)
PRODUCT CODE:	FQH; FRO
PREDICATE DEVICE:	Irrisept® Wound Debridement and Cleansing System (K080779) • Product Code FQH (Jet Lavage); Class II (21 CFR 880.5475) • Product Code FRO (Dressing, Wound, Drug); Unclassified (pre-amendment) Applicant: Irrimax Corporation

DEVICE DESCRIPTION:

Irrisept® Wound Debridement and Cleansing System 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:

The Irrisept Wound Debridement and Cleansing System is a wound cleansing delivery system. The mechanical action effectively loosens and removes wound debris.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The Irrisept that is the subject of this 510(k) is substantially equivalent to its predicate, predecessor K080779 Irrisept. This is a catch-up 510(k) submission intended to update the Irrisept record at FDA with the changes that have been implemented in the subject product. As such, the intended use/indications remain identical to that for the cleared product. Further, the implemented changes were primarily to be responsive to user feedback, capture the now available longer-term shelf-life data, or reflect a need to change a supplier or manufacturing contractor. These are captured in the comparison table below.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS		
Comparison Feature	**Cleared Irrisept Product (K080779)**	**Subject Irrisept Product (K202222)**
Intended Use/ Indications for Use	The Irrisept Wound Debridement and Cleansing System is a wound cleansing delivery system. The mechanical action effectively loosens and removes wound debris.	Identical
Rx only	Prescription Product	Identical
Single Use	Single Use	Identical
Mechanism of Action	The mechanical action of fluid across the wound removes wound debris.	Identical.
Components and Materials	• Polypropylene bottle • Solution • Polycarbonate applicator	• New supplier for Chlorhexidine Gluconate • New supplier for polycarbonate
Solution Composition	0.05% Chlorhexidine Gluconate in 99.95% Sterile Water for Irrigation, USP	Identical
Container Design	450 mL BFS bottle delivers fluid by manual compression	Identical
Applicator Design	Multi-port applicator that threads onto bottle.	• Multi-port applicator that threads onto bottle and with a longer tip. • Change to a higher capacity manufacturing mold
Biocompatibility	Conforms to ISO 10993-1 for a surface device with breached or compromised surface contact and a limited contact duration (≤ 24 hours)	Identical

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS		
Comparison Feature	**Cleared Irrisept Product (K080779)**	**Subject Irrisept Product (K202222)**
Manufactured using Aseptic Techniques	• Solution is manufactured using Blow-Fill-Seal (BFS) aseptic processing. • Solution labeled as Sterile.	Identical BFS process • New contract manufacturer • Changed to a higher capacity BFS manufacturing mold
Non-Pyrogenic	Solution	Solution and applicator Endotoxin Limit ≤ 20 EU/device (<0.045 EU/mL for 450 mL)
Packaging	1. Packaged applicator in Tyvek® film pouch 2. Protective PETG tube added over bottle cap to protect bottle cap during shipment 3. Sterilized applicator and bottle-filled solution are then packaged in a shelf box.	• Changed manufacturing final step for protective PETG tube • Bottle-filled solution and applicator are packaged together in CSR wraps and Tyvek® header pouch for sterilization • New contract manufacturer
Sterilization	Packaged applicator conforms to ISO 11135 and ISO 10993-7 for EO sterilization, whereas the solution is aseptically processed	The bottle and applicator are EO-sterilized and conform to ISO 11135 and ISO 10993-7, whereas the solution is aseptically processed
Shelf-Life	Six-month shelf-life.	Two-year shelf-life
Labeling	Labeling consists of: 1) Bottle Label 2) Applicator label 3) Package Label - Shelf Box Label 4) Shipping Box Label	Labeling consists of: 1) Bottle Label 2) Package Label - Front 3) Package Label - Back 4) Shipping Box Label

The differences between the two versions of Irrisept do not raise different questions of safety and effectiveness and have been confirmed through testing.

PERFORMANCE TESTING:

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

CONCLUSIONS:

In conclusion, Irrimax has demonstrated through performance testing that the subject Irrisept is substantially equivalent to its predicate Irrisept product in intended use and technological characteristics.