May 31, 2022

Inopro Inc
Alain Lefebvre
President
800 rue Sud Porte A
Cowansville, Quebec J2K 2Y3
Canada

Re: K210987
Trade/Device Name: IRRIGO Wound Wash Jet System
Regulatory Class: Unclassified
Product Code: FRO, FQH
Dated: March 10, 2021
Received: April 1, 2021

Dear Alain Lefebvre:

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.
Acting 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)*
K210987

Device Name
IRRIGO Wound Wash Jet System

Indications for Use *(Describe)*
IRRIGO Wound Wash Jet System is intended for use by or under the direction of a professional healthcare provider in moistening and lubricating absorbent wound dressings, cleansing, and maintaining a moist wound environment for traumatic wounds such as pressure sores, leg ulcers of diabetic and vascular origin, cuts, abrasions, and minor burns.

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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Section 5: 510(k) Summary [K210987]

I. Regulatory Sponsor

Inopro, Inc.
800 rue Sud Porte A
Cowansville Quebec J2K 2Y3 Canada

Contact: Alain Lefebvre
Title: President
Phone: (514) 438-8481
Email: alefebvre@inopro.ca

II. Date Prepared

March 2, 2022

III. Type of 510(k) Submission

Traditional

IV. Device Identification

Trade/Proprietary Name:	IRRIGO Wound Wash Jet System
Common Name:	Dressing, Wound, Drug
Classification:	Unclassified
FDA Product Code:	FRO, FQH
Review Panel:	General Hospital

V. Legally Marketed Predicate Device(s)

Primary Predicate
K090848 Premier Saline Wound Wash

Secondary Predicate
K082330 Primary Care Solutions Sterile Water and Sterile Saline

These predicates have not been subject to a design-related recall.

VI. Device Description

IRRIGO Wound Wash Jet System is a sterile single patient use jet lavage medical device that consists of 0.9% USP Sodium Chloride solubilized in USP Purified Water for Irrigation and packaged in a food grade compressible translucent LDPE 2oz (60mL) bottle with a LPDE luer-lock type tip spray insert and an HPDE colored cap.

The mechanism of action of the solution moving across the wound aids in the removal of foreign material, such as dirt and debris, as well as any necrotic tissue, wound exudates, and other extraneous matter. IRRIGO Wound Wash Jet System can generate upto 15 psi of stream pressure.

No preservatives are added since the finished device is sterilized by gamma irradiation.

VII. Indications for Use

IRRIGO Wound Wash Jet System is intended for use by or under the direction of a professional healthcare provider in moistening and lubricating absorbent wound dressings, cleansing, and maintaining a moist wound environment for traumatic wounds such as pressure sores, leg ulcers of diabetic and vascular origin, cuts, abrasions, and minor burns.

For Prescription Use Only.

VIII. Substantial Equivalence Comparison Table

Device Name	**IRRIGO Wound Wash Jet System**	**Premier Sterile Saline Wound Wash**	**Primary Care Solutions Sterile Water and Sterile Saline**	**Substantial Equivalent (SE)**
	Subject Device	**Primary Predicate**	**Secondary Predicate**	
510(k) #	K210987	K090848	K082330	----------
Classification Product Code	FRO, FQH	FRO, FQH	FRO, FQH, JOL	**SE**
Fluid Composition	0.9% sodium chloride (USP) and purified water (USP)	0.9% sodium chloride (USP) and purified water (USP)	0.9% sodium chloride (USP) and sterile water for irrigation (USP)	**SE**
Indications For Use	**Rx:** IRRIGO Wound Wash Jet System is intended for use by or under the direction of professional healthcare provider in moistening and lubricating absorbent wound dressings, cleansing, and maintaining a moist wound environment for traumatic wounds such as pressure sores, leg ulcers of diabetic and vascular	**Rx:** Saline Wound Wash is intended for use by or under the direction of a professional healthcare provider in moistening and lubricating absorbent wound dressings, cleansing, and maintaining a moist wound environment for traumatic wounds such as pressure sores, leg ulcers of diabetic and vascular origin, cuts,	**Rx:** Moisturizing of Wound Dressings, Device Irrigation and Jet Lavage for Tissue Debridement	**SE;** Subject device - Irrigo is for Rx Only.

	origin, cuts, abrasions, and minor burns.	abrasions, and minor burns. **OTC:** Saline Wound Wash is intended for use in moistening and lubricating absorbent wound dressings and for cleansing minor wounds, scrapes and minor burns. If redness, swelling or bleeding continues, please seek the help of nurse, nurses aid, doctor, or other medical professional.		
Description	IRRIGO Wound Wash Jet System is a sterile single patient use jet lavage medical device that consists of 0.9% USP Sodium Chloride solubilized in USP Purified Water for Irrigation and packaged in a food grade compressible translucent LDPE 2oz (60mL) bottle with a LPDE luer-lock type tip spray insert and an HPDE colored cap.	Saline Wound Wash is a multi-use, isotonic, sterile saline solution packaged in a bag-in-can aerosol system. Actuation of the device (product can) delivers a consistent flow of sterile isotonic saline solution at published safe and effective wound impact pressures of 4 to 15 psi (Clinical Practice Guideline Number 15 AHCPR, US Health and Human Services).	This device is USP purified water or saline sealed in 100mL HDPE bottles or 120mL HIPS cups.	**SE;** Subject device - Irrigo is similar to both predicates. Difference is Primary Predicate is a bag-in-can aerosol system; Subject device is in a non-aerosol bottle. Subject and primary predicate capable of delivering upto 15 psi of pressure; Unknown for Secondary Predicate.

Mechanism of Action	The mechanical action of isotonic saline solution moving across the wound aids in the removal of foreign material, such as dirt and debris, as well as any necrotic tissue, wound exudates and other extraneous matter.	The mechanical action of isotonic saline solution moving across the wound aids in the removal of foreign material, such as dirt and debris, as well as any necrotic tissue, wound exudates and other extraneous matter.	The mechanical action of isotonic saline solution moving across the wound aids in the removal of foreign material, such as dirt and debris, as well as any necrotic tissue, wound exudates and other extraneous matter.	**SE**
Preservative	No preservatives are added since the finished device is sterilized by gamma irradiation.	No preservatives are added since the finished device is sterilized by gamma irradiation.	Unknown	**SE;** Subject and Primary Predicate; Unknown for Secondary Predicate
Packaging	IRRIGO Wound Wash Jet System is a sterile single patient use jet lavage medical device that consists of 0.9% USP Sodium Chloride solubilized in USP Purified Water for Irrigation and packaged in a food grade compressible translucent LDPE 2oz (60mL) bottle with a LPDE luer-lock type tip spray insert and an HPDE colored cap.	Saline Wound Wash is an aerosol bag-in-can system. The propellant, compressed air, is charged into the container between the bag and the can creating a means to dispense the contents of the bag, isotonic sterile saline solution. The bag is a 4-layer laminate system including a sandwiched polyethylene layer establishing an impermeable barrier between the propellant (compressed air) and the bag contents (sterile isotonic saline). The isotonic saline solution of is in contact with either a	100mL HDPE bottles or 120mL HIPS cups	**SE;** Subject and Secondary Predicate similar, Primary predicate – aerosol bag-in-can system

		0.9% sodium chloride solution prepared from sodium chloride, USP, and purified water, USP.		
Sterilization Method	Gamma	Gamma	Gamma	**SE**
Single Use/Multi-Use	Single Use	Multi Use	Single Use	**SE**; Subject Device is for Single Use Only.
Rx or OTC	Rx	Both	Rx	**SE;** Subject Device is for Rx Use Only.

IX. Summary of Bench Testing

IRRIGO Wound Wash is tested against the following established specifications and standards:

- USP 43-NF38:2020 Sodium Chloride Irrigation
- USP 43-NF38:2020 <71> Sterility Tests
- USP 43-NF38:2020 <85> Bacterial Endotoxins Test
- USP 43-NF38:2020 Purified Water
- USP 43<541> Titrimetry – Sodium Chloride Assay
- ANSI AAMI ISO 11137-1 Sterilization of healthcare products -Radiation – Part 1 Requirements for development, validation, and routine control of a sterilization process for medical devices
- ANSI AAMI ISO 11137-2 Sterilization of healthcare products -Radiation – Part 2 Establishing the sterilization dose.
- ANSI AAMI ST67:2019 Sterilization of healthcare products – Requirements and guidance for selecting a sterility assurance level (SAL)
- IRRIGO PSI Testing/Internal Pressure Curves
- Packaging integrity leak test

IRRIGO Wound Wash Jet System is tested against established specifications and meets Biocompatibility requirements:

- ISO 10993-5 Cytotoxicity
- ISO 10993-10 Intracutaneous Reactivity
- ISO 10993-10 Skin Sensitization
- ISO 10993-11 Acute Systemic Toxicity
- <USP 151> Material-Mediated Pyrogenicity

X. Statement of Substantial Equivalence

The subject device and predicate devices are jet lavage devices used to clean a wound by a pulsatile jet of sterile fluid. These devices have the same intended use and similar technological characteristics. IRRIGO Wound Wash Jet System has the same intended use and indications for use as the primary and secondary predicate devices. Any minor differences in the technological features of the subject device when compared to the predicate devices have been evaluated through safety and performance testing and other verification and validation testing activities such that the information demonstrates that the subject device, when compared to the predicted devices, does not raise any new questions of safety and effectiveness. IRRIGO Wound Wash Jet System has been determined to be substantially equivalent to the predicate devices.