October 23, 2026

Poly Medicure Limited
% Sunita Teekasingh
Regulatory Consultant
GSA2 Group, LLC
8049 Hayes St. N. E.
Spring Lake Park, Minnesota 55432

Re: K261670
Trade/Device Name: Polymed TUR Irrigation Set, Single Spike, Tubing 90" with Luer Lock - Sterile (30031); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 90" with Luer Lock - Sterile (30032); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing, 90" with Luer Lock- Sterile (30033); Polymed TUR Irrigation Set, Single Spike, Tubing 80", with Luer Lock - Sterile (30034); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 80", with Luer Lock- Sterile (30035); Polymed TUR Irrigation Set, Y- Type, 4 Leads, Tubing 80" with Luer Lock- Sterile (30036); Polymed TUR Irrigation Set, Single Spike, Tubing 100" with Luer Lock – Sterile (30037); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 100" with Luer Lock - Sterile (30038); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing 100" with Luer Lock - Sterile (30052); Polymed TUR Irrigation Set, Single Spike, Tubing 90" without Luer Lock - Sterile (30053); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing, 90" without Luer Lock- Sterile (30054); Polymed TUR Irrigation Set, Single Spike, Tubing 80", without Luer Lock – Sterile (30055); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 80", without Luer Lock- Sterile (30056); Polymed TUR Irrigation Set, Y- Type, 4 Leads, Tubing 80" without Luer Lock- Sterile (30057); Polymed TUR Irrigation Set, Single Spike, Tubing 100" without Luer Lock - Sterile (30058); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 100" without Luer Lock – Sterile (30059); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing 100" without Luer Lock - Sterile (30070); Polymed TUR Irrigation Set, Single Spike, Tubing 90" with Luer Lock – Non Sterile (30071); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 90" with Luer Lock- Non Sterile (30072); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing, 90" with Luer Lock- Non Sterile (30073); Polymed TUR Irrigation Set, Single Spike, Tubing 80", with Luer Lock- Non Sterile

(30074); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 80", with Luer Lock- Non Sterile (30075); Polymed TUR Irrigation Set, Y- Type, 4 Leads, Tubing 80" with Luer Lock- Non Sterile (30076); Polymed TUR Irrigation Set, Single Spike, Tubing 100" with Luer Lock - Non Sterile (30077); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 100" with Luer Lock- Non Sterile (30078); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing 100" with Luer Lock- Non Sterile (30079); Polymed TUR Irrigation Set, Single Spike, Tubing 90" without Luer Lock- Non Sterile (30080); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 90" without Luer Lock- Non Sterile (30081); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing, 90" without Luer Lock- Non Sterile (30082); Polymed TUR Irrigation Set, Single Spike, Tubing 80", without Luer Lock- Non Sterile (30083); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 80", without Luer Lock- Non Sterile (30084); Polymed TUR Irrigation Set, Y- Type, 4 Leads, Tubing 80" without Luer Lock- Non Sterile (30085); Polymed TUR Irrigation Set, Single Spike, Tubing 100" without Luer Lock - Non Sterile (30086); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 100" without Luer Lock- Non Sterile (30087); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing 100" without Luer Lock- Non Sterile (30088)

Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: LJH
Received: September 21, 2026

Dear Sunita Teekasingh:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administratio (FDA) may publish further announcements concerning your device in the Federal Register.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

BONHYE KOO -S

For
Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology 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)*
K261670

Device Name
TUR Irrigation Set

Indications for Use *(Describe)*
Device Name: Polymed TUR Irrigation Set, Single Spike, Tubing 90" with Luer Lock - Sterile (30031); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 90" with Luer Lock - Sterile (30032); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing, 90" with Luer Lock- Sterile (30033); Polymed TUR Irrigation Set, Single Spike, Tubing 80", with Luer Lock - Sterile (30034); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 80", with Luer Lock- Sterile (30035); Polymed TUR Irrigation Set, Y- Type, 4 Leads, Tubing 80" with Luer Lock- Sterile (30036); Polymed TUR Irrigation Set, Single Spike, Tubing 100" with Luer Lock - Sterile (30037); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 100" with Luer Lock - Sterile (30038); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing 100" with Luer Lock - Sterile (30052); Polymed TUR Irrigation Set, Single Spike, Tubing 90" without Luer Lock - Sterile (30053); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing, 90" without Luer Lock- Sterile (30054); Polymed TUR Irrigation Set, Single Spike, Tubing 80", without Luer Lock - Sterile (30055); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 80", without Luer Lock- Sterile (30056); Polymed TUR Irrigation Set, Y- Type, 4 Leads, Tubing 80" without Luer Lock- Sterile (30057); Polymed TUR Irrigation Set, Single Spike, Tubing 100" without Luer Lock - Sterile (30058); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 100" without Luer Lock - Sterile (30059); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing 100" without Luer Lock - Sterile (30070); Polymed TUR Irrigation Set, Single Spike, Tubing 90" with Luer Lock - Non Sterile (30071); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 90" with Luer Lock- Non Sterile (30072); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing, 90" with Luer Lock- Non Sterile (30073); Polymed TUR Irrigation Set, Single Spike, Tubing 80", with Luer Lock- Non Sterile (30074); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 80", with Luer Lock- Non Sterile (30075); Polymed TUR Irrigation Set, Y- Type, 4 Leads, Tubing 80" with Luer Lock- Non Sterile (30076); Polymed TUR Irrigation Set, Single Spike, Tubing 100" with Luer Lock - Non Sterile (30077); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 100" with Luer Lock- Non Sterile (30078); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing 100" with Luer Lock- Non Sterile (30079); Polymed TUR Irrigation Set, Single Spike, Tubing 90" without Luer Lock- Non Sterile (30080); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 90" without Luer Lock- Non Sterile (30081); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing, 90" without Luer Lock- Non Sterile (30082); Polymed TUR Irrigation Set, Single Spike, Tubing 80", without Luer Lock- Non Sterile (30083); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 80", without Luer Lock- Non Sterile (30084); Polymed TUR Irrigation Set, Y- Type, 4 Leads, Tubing 80" without Luer Lock- Non Sterile (30085); Polymed TUR Irrigation Set, Single Spike, Tubing 100" without Luer Lock - Non Sterile (30086); Polymed TUR Irrigation Set, Y-Type, 2 Leads, Tubing 100" without Luer Lock- Non Sterile (30087); Polymed TUR Irrigation Set, Y-Type, 4 Leads, Tubing 100" without Luer Lock- Non Sterile (30088)

The TUR Irrigation Set is intended to deliver irrigating solutions from a fluid container directly to the irrigation site during bladder irrigation and various endoscopic procedures, including cystoscopy, and transurethral resection (TUR) procedures.

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 PER 807.92(C)

1. ADMINISTRATIVE INFORMATION

Submitter Information	
Device Name	Polymed TUR Irrigation Set
Manufacturer	Poly Medicure Ltd. PA 010-018, 010-019, Mahindra World City (Jaipur) Ltd, Multi product SEZ, Jaipur Rajasthan-302237, India +91-129-3355070
Official Correspondent	Sunita Teekasingh RN, BSN, CCRN, MSc Regulatory Consultant, GSA2 Group LLC Minneapolis, Minnesota Phone: 612-814-7999 Email: gsa2groupllc@gmail.com
Date 510(k) summary was prepared	October 23, 2026
SUBJECT DEVICE	
FDA Product Code	LJH
FDA Regulation Number	21 CFR 876.5130
FDA Classification Name	Urological catheter and accessories.
Classification Panel	Gastroenterology/Urology
Common Name	Irrigation Set
FDA Classification	Class II
PREDICATE DEVICE IDENTIFICATION	
Predicate Manufacturer	International Medsurg Connections, Inc.
Predicate Trade Name	TUR, Arthroscopic, Cystoscopy Irrigation Sets
Predicate Common Name	Irrigation Sets
Predicate 510(k) Number	K023808 Note: The predicate has not been subject to a design-related recall.
FDA Classification	Class II
Predicate FDA Product Code	LJH, HRX
Predicate FDA Regulation Number	21 CFR 876.5130, 21 CFR 888.1100
Predicate FDA Classification Name	System, Irrigation, Urological / Arthroscope
Predicate Classification Panel	Gastroenterology/Urology and Orthopedic

2. DEVICE DESCRIPTION

The TUR Irrigation Set is a gravity-fed administration system designed to deliver irrigation solutions from a fluid container to an irrigation site during bladder irrigation and various endoscopic procedures, including cystoscopy, and transurethral resection (TUR) procedures. The device is available in three primary configurations: One-Way (Single Spike), Two-Way (Y-Type), and Four-Way (4 leads). Key components include ABS spikes for container access, PVC drip chambers for flow monitoring, PVC main tubing (available in 80, 90, and 100-inch lengths), and a 15 cm silicone segment for pump compatibility. Flow is controlled via integrated manual C-clamps and a roller-style regulating clamp. The distal end is equipped with either a tapered step connector, silicone tubing or a Male Luer Lock connector.

Sterile versions are EO-sterilized to a Sterility Assurance Level (SAL) of 10^{-6} and supplied in a validated sterile barrier pouch. Non-sterile versions are identical in design and materials and are intended for third-party kitting; they are validated to withstand one (1) EO sterilization cycle performed by the kit manufacturer.

3. INDICATIONS FOR USE

The TUR Irrigation Set is intended to deliver irrigating solutions from a fluid container directly to the irrigation site during bladder irrigation and various endoscopic procedures, including cystoscopy, and transurethral resection (TUR) procedures.

4. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The following table provides a side-by-side comparison of the TUR Irrigation Set and the predicate device (K023808) to establish substantial equivalence in terms of intended use and technological characteristics.

Characteristic	Subject Device: TUR Irrigation Set	Predicate: K023808	SE Determination
Regulation Number	21 CFR 876.5130	21 CFR 876.5130 21 CFR 888.1100	Substantially Equivalent for this Indication
Product Code	LJH	LJH, HRX	Substantially Equivalent for this Indication
Indications for Use	The TUR Irrigation Set is intended to deliver irrigating solutions from a fluid container directly to the irrigation site during bladder irrigation and various endoscopic procedures, including cystoscopy and transurethral resection (TUR) procedures.	This device is intended for delivery of irrigation solutions from the fluid container to the irrigation site during bladder irrigation or endoscopic procedures including cystoscopy, transurethral resection (TUR) and arthroscopic procedures. This tubing segment is connected to the endoscope for delivery of solution to the irrigation site such as the bladder or knee.	Substantially Equivalent
Intended Use	Delivery of irrigation solutions during bladder irrigation, cystoscopy, and TUR. Can be used with endoscopic devices	Delivery of irrigation solutions during, bladder irrigation, cystoscopy, TUR and arthroscopic procedures. Can be used with endoscopic devices	Substantially Equivalent for this Indication

Characteristic	Subject Device: TUR Irrigation Set	Predicate: K023808	SE Determination
Design / Type	Gravity-fed irrigation set	Gravity-fed irrigation set	Identical
Configurations	One-Way, Two-Way, Four-Way	Single spike	Different
Connection Type	Luer connectors and non-luer step connectors	Luer connectors	Different
Tubing Lengths	80, 90, 100 inches (Luer and non-luer sterile and non-sterile)	Comparable lengths	Substantially Equivalent
Tubing Materials	PVC, Silicone, ABS, PP	Polymeric (Polyurethane)	Different
Principle of Operation	Gravity-fed hydrostatic pressure	Gravity-fed hydrostatic pressure	Substantially Equivalent
Sterilization	Ethylene Oxide (EO), SAL 10^{-6} or provided non-sterile to be EO sterilized by the kit manufacturer (validated for 1 cycle)	Ethylene Oxide (EO)	Equivalent (The non-sterile configurations are identical in design and materials and are validated to withstand the same EO sterilization method).

5. SUMMARY OF NON-CLINICAL PERFORMANCE DATA

a. Bench Testing:

Testing was conducted on the worst-case configuration (4-way, 100-inch). Results demonstrated compliance with internal specifications and consensus standards:

- **Tensile Strength:** 161.10 N (Pass)
- **Flow Rate:** 612.62 mL/min (Pass)
- **Luer Connector:** Complies with *ISO 80369-7 :2021- Small-bore connectors for liquids and gases in healthcare applications*

In addition to the above, the following tests were conducted on the device:

- Leakage from joints
- Spike Geometry
- Flow Regulator Function
- Kink Resistance
- Dimensional Verification
- Visual Inspection

b. Biocompatibility

The subject TUR Irrigation Sets, when used as intended, is considered as external communicating device contacting blood path, indirect for a prolonged duration (> 24 h to 30 d). Per ISO 10993-1 "*Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*", the device was evaluated for the following endpoints: cytotoxicity, intracutaneous irritation, sensitization, acute systemic toxicity, subacute/sub-chronic systemic toxicity, material-mediated pyrogenicity, and hemocompatibility.

c. Sterilization

Validated via 30% EO (Half-Cycle Overkill) per *ISO 11135:2014 - /Amd 1:2018 Sterilization of health-care products - Ethylene Oxide-Requirements for the development, validation and routine control of a sterilization process for medical devices - Amendment 1: Revision of A.* to a SAL of 10^{-6}. EO/ECH residuals are within *ISO 10993-7- biological evaluation of medical devices- Part 7: Ethylene oxide sterilization residuals* limits.

d. Shelf Life

Shelf life of 3 years was validated through accelerated aging (*ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices*) and distribution simulation (*ASTM D4169-23 Standard Practice for Performance Testing of Shipping Containers and Systems*), followed by sterile barrier integrity testing.

e. Packaging Validation

Packaging validation included seal strength (*ASTM F88-23- Standard Test Method for Seal Strength of Flexible Barrier Materials*), dye penetration (*ASTM F1929-23- Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration*), and visual inspection (*ASTM F1886- 25- Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection*). All results met acceptance criteria.

6. DISCUSSION OF SIMILARITIES AND DIFFERENCES

a. Indications for Use and Clinical Application

The TUR Irrigation Set has similar indications for use as the predicate device (K023808). Both devices are intended for the delivery of irrigation fluids to surgical sites during urological endoscopic procedures. There are no differences in the intended patient population, clinical environment or operating principles.

b. Technological Characteristics

The TUR Irrigation Set and predicate device share the same fundamental technological characteristics, including gravity-fed hydrostatic operation, polymeric tubing construction, drip chamber flow monitoring, manual flow regulation, and similar fluid-path components. The subject device is available in One-Way, Two-Way, and Four-Way whereas the predicate only offers a One-way configuration. Both the subject and the predicate feature luer connectors, while the subject device utilizes *ISO 80369-7:2021* compliant luer connectors. The non-luer step connectors have been validated on dimensional verification and mechanical/functional performance. Additionally, while the predicate device is only provided sterile, the subject device is offered in both sterile and non-sterile configurations. The non-sterile configurations are identical in design and materials to the sterile configurations and have been validated to withstand a single Ethylene Oxide (EO) sterilization cycle by the third-party kit manufacturer, ensuring material and mechanical integrity are not compromised. These differences do not alter the operating principle or raise different questions of safety or effectiveness.

c. Materials

The TUR Irrigation Set is manufactured from PVC, Silicone, ABS, and Polypropylene. These materials are substantially equivalent to those used in the predicate.

d. Performance Testing

Non-clinical bench testing demonstrates that the subject device meets all functional requirements and is as safe and effective as the predicate device.

7. CONCLUSION

Based on the comparison of technological characteristics and the supporting data provided in this submission, the technological differences do not raise different questions of safety or effectiveness. Non-clinical testing shows that the subject device is as safe and effective as the predicate device. Therefore, the subject devices are substantially equivalent to the predicate device (K023808).