June 27, 2025

Multi4 Medical AB
% Erin Gontang
Senior Consultant
RQM+
2790 Mosside Blvd, Suite #800
Monroeville, Pennsylvania 15146

Re: K250522
Trade/Device Name: Multi4 System
Regulation Number: 21 CFR 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and accessories
Regulatory Class: II
Product Code: FAS, GEI , KQT , FJL , FBK
Dated: February 21, 2025
Received: June 4, 2025

Dear Erin Gontang:

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.

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,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
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.

Submission Number *(if known)*

K250522

Device Name

Multi4 System

Indications for Use *(Describe)*

The Multi4 System is intended for use by trained urologists for endoscopically controlled tissue resection and coagulation, and removal of bladder tumors (TURBT) via suction channel under controlled flow conditions following resection using a monopolar resectoscope. The Multi4 System is also intended to deliver injectable materials into the urinary bladder wall during transurethral endoscopic 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.

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

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510(k) Summary
K250522

DATE PREPARED
June 4, 2025

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DEVICE INFORMATION

Trade/Proprietary Name:	Multi4 System
Classification Name:	Electrode, Electrosurgical, Active, Urological
Regulation Number:	21 CFR 876.4300
Common Name:	Endoscopic electrosurgical unit and accessories; Electrosurgical cutting and coagulation device; Endoscope and accessories
Device Class:	Class II
Product Code:	FAS, KQT, GEI, FBK, FJL
Classification Panel:	Gastroenterology/Urology
Premarket Review:	Reproductive, Gynecology and Urology Devices (DHT3B)

PREDICATE DEVICE IDENTIFICATION
The Multi4 System is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Predicate*
K191341	Veloxion System / Corinth MedTech, Inc.	Primary
K192498	Single Use Injection / Olympus Medical Systems	Secondary

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION

The Multi4 System is an electrosurgical system used during urethral resection procedures of adult patients. The system, intended to remove and collect tissue from the bladder, includes a single-use electrosurgical instrument, known as the Multi4 B, as well as the reuseable Multi4 Pump. The Multi4 Pump administers energy from an external electrosurgical unit to the handheld Multi4 B instrument, which has electrosurgical functions and allows for fluid transport and tissue sample collection. The Multi4 B instrument accesses the bladder through the working channel of a commercially available cystoscope. The Multi4 System is a prescription device intended for use in professional healthcare facilities by healthcare professionals (HCPs).

INDICATIONS FOR USE STATEMENT

The Multi4 System is intended for use by trained urologists for endoscopically controlled tissue resection and coagulation, and removal of bladder tumors (TURBT) via suction channel under controlled flow conditions following resection using a monopolar resectoscope. The Multi4 System is also intended to deliver injectable materials into the urinary bladder wall during transurethral endoscopic procedures.

SUMMARY OF NON-CLINICAL TESTING

The following testing was performed to evaluate the safety and effectiveness of the Multi4 System.

- Software Verification and Validation Testing performed per IEC 62304, and documentation provided per FDA's *Guidance for Industry and FDA Staff: Content of Premarket Submissions for Device Software Functions (Issued June 14, 2023).*
- Sterility Testing
- Packaging Testing
- Shelf-life Testing
- Biocompatibility Testing
    - Cytotoxicity, Irritation, Sensitization, Acute Systemic Toxicity, Pyrogenicity
- Electrical Safety & EMC:
    - IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, and IEC 60601-2-2
- Integrity Testing
- Functional Testing
    - Cut and coagulation, aspiration, irrigation, injection
- Dimensional Inspection and Testing
- Simulated Use Testing

EQUIVALENCE TO PREDICATE DEVICE

The subject device has a similar design and dimensions and uses similar or identical materials as the devices cleared in K191341 and K192498. The subject device also has the same intended use and similar technological characteristics as the devices cleared in K191341 and K192498.

Based on the testing performed, including biocompatibility, sterilization validation, packaging validation, shelf-life validation, EMC and electrical safety and EMC testing, software verification and validation testing, and non-clinical performance bench testing, it can be concluded that the subject device does not raise different questions of safety or effectiveness compared to the predicate devices. The testing performed demonstrates that the subject device is as safe and effective as the

predicate devices, and the similar indications for use, technological characteristics, and performance characteristics for the proposed Multi4 System are assessed to be substantially equivalent to the predicate devices. The Multi4 System is substantially equivalent to the predicate devices based on the information summarized here:

	Subject Device	Predicate Device	Predicate Device
Device Name	**Multi4 System**	**Veloxion System**	**Single Use Injector**
Manufacturer Name	**Multi4 Medical AB**	**Corinth MedTech, Inc.**	**Olympus Medical Systems Corp.**
510(k) Number	**K250522**	**K191341**	**K192498**
Regulation	21 CFR 876.1500 - Endoscope and accessories 21 CFR 876.4370 - Gastroenterology-urology evacuator 21 CFR 878.4400 - Electrosurgical cutting and coagulation device and accessories 21 CFR 876.4300 - Endoscopic electrosurgical unit and accessories	21 CFR 876.1500 - Endoscope and accessories 21 CFR 876.4370 - Gastroenterology-urology evacuator 21 CFR 878.4400 - Electrosurgical cutting and coagulation device and accessories	21 CFR 876.1500 - Endoscope and accessories
Regulation	Endoscope and accessories	Endoscope and accessories	Endoscope and accessories
Product Code(s)	FJL - Resectoscope KQT - Evacuator, Gastro-Urology GEI - Electrosurgical, Cutting & Coagulation & Accessories FAS - Electrode, Electrosurgical, Active, Urological FBK - Endoscopic Injection Needle, Gastroenterology-Urology	FJL - Resectoscope KQT - Evacuator, Gastro-Urology GEI - Electrosurgical, Cutting & Coagulation & Accessories	FBK - Endoscopic Injection Needle, Gastroenterology-Urology
Classification	Class II	Class II	Class II
Indications for Use Statement	The Multi4 System is intended for use by trained urologists for endoscopically controlled tissue resection and coagulation, and removal of bladder tumors (TURBT) via suction channel under controlled flow conditions following resection using a monopolar resectoscope. The Multi4 System is also intended to deliver injectable materials into the urinary bladder wall during transurethral endoscopic procedures.	The Veloxion System is intended for use by trained urologists for endoscopically controlled tissue chip resection and coagulation, and removal of prostate adenomas and bladder tumors (TURBT) via suction channel under continuous flow conditions following resection using a bipolar resectoscope.	This instrument has been designed to be used with an Olympus endoscope to deliver injectable materials into the urinary bladder wall during the transurethral endoscopic procedures.

Device Description	The Multi4 System consists of the following components: • Multi4 Pump (with Integrated Fluid Control) o Footswitch • Multi4 B o Resectoscope & Needle o Simple4tainer (For collection of gross resected tissue pieces for pathology)	The Veloxion System consists of the following components: • Veloxion Controller (with Integrated Fluid Control) o Footswitch • Veloxion Resectoscope • Veloxion Fluid Set • Waste Management Tubing • Tissue Catch (For collection of gross resected tissue pieces for pathology)	The Single Use Injector has been designed to be used with an Olympus endoscope to deliver injectable materials into the urinary bladder wall during the transurethral endoscopic procedures. The Single Use Injector device is provided in a sterile package.
Target Population	Adults	Adults	Adults
Sterile/ Non-sterile	Sterile; Gamma	Sterile; Unknown	Sterile; Unknown
Use Environment	Healthcare Facilities	Healthcare Facilities	Healthcare Facilities
Energy Type; Monopolar or Bipolar	Radiofrequency; Monopolar	Radiofrequency; Bipolar	N/A
RF Function	Cut, Coagulation	Cut, Coagulation	N/A
Control of cavity pressure?	The urologist manages the irrigation and fluid control during the procedure.	The device uses a pressure monitor to evaluate cavity pressure during the procedure.	N/A
Irrigation Fluid	Water	Saline	N/A
Pump	Dual Action (Irrigation, Aspiration)	Dual Action (Irrigation, Aspiration)	N/A
Testing	Biocompatibility Testing Sterility Testing Packaging Testing Shelf-life Testing EMC/Electrical Safety Testing Software V&V Testing Performance Testing – Bench and Simulated Use	Biocompatibility Testing Sterility Testing Packaging Testing Shelf-life Testing EMC/Electrical Safety Testing Software V&V Testing Performance Testing – Bench and Simulated Use	Biocompatibility Testing Sterility Testing Packaging Testing Shelf-life Testing Performance Testing – Bench
Functional Testing	Cut & Coagulation Aspiration Irrigation Injection	Cut & Coagulation Aspiration Irrigation Pressure Control	 Injection
Needle Width	27G	N/A	27G
Needle Working Length	716 mm	N/A	971 mm
Needle Length	11 mm (maximum)	N/A	4 mm
Tip Shape of Needle	Lancet Point	N/A	Lancet Point

CONCLUSION

Based on the testing performed, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The Multi4 System is considered safe and effective for its intended use. The similar technological characteristics and performance characteristics for the Multi4 System are assessed to be substantially equivalent to the predicate devices.