August 7, 2026

Roen Surgical, Inc.
% Justin Gracyalny
Senior Manager, Regulatory and Technical Compliance
Secure BioMed Evaluations
7828 Hickory Flat Hwy
Suite 120
Woodstock, Georgia 30188

Re: K253505
Trade/Device Name: Zamenix™ P
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: FGB
Dated: July 10, 2026
Received: July 10, 2026

Dear Justin Gracyalny:

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 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,

MARK TRUMBORE -S

Digitally signed by MARK TRUMBORE -S
Date: 2026.08.07 14:09:01 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General 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)*
K253505

Device Name
Zamenix™ P

Indications for Use *(Describe)*
Zamenix™ P is indicated for endoscopic examination in the urinary tract with transurethral access and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures. The device is intended for use in patients aged 22 or older.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

**510(k) SUMMARY:**
Roen Surgical, Inc. Zamenix™ P

| | |
|---|---|
| **Date Prepared** | August 7, 2026 |
| **Sponsor** | Roen Surgical, Inc.<br>193, Munji-ro, Yuseong-gu<br>T122, Truth Hall<br>Daejeon, Republic of Korea 34051 |
| **510(k) Contact** | Secure BioMed Evaluations<br>Justin Gracyalny, MSE<br>7828 Hickory Flat Highway, Suite 120<br>Woodstock, GA 30188<br>770-837-2681<br>Regulatory@SecureBME.com |
| **Trade Name** | Zamenix™ P |
| **Common Name** | Ureteroscope and Accessories, Flexible/rigid |
| **Product Code – Device – Regulation Number** | FGB – Endoscope and accessories (21 CFR §876.1500). |
| **Primary Predicate** | K233700 Elmed Elektronik ve Medikal Sanayi ve Ticaret Anonim Sirketi Avicenna Roboflex |
| **Reference Device** | K200238 ControlRad Inc. Sterile Cover<br>K170898 Cook Incorporated Wittich Nitinol Stone Basket |

The predicate device has not been subject to a design-related recall.

## Device Description

The Zamenix™ P is a robotic ureteroscopy system intended for use in and indicated for endoscopic examination in the urinary tract with transurethral access and can be used to examine the interior of the kidney, and using additional accessories, to perform various diagnostic and therapeutic procedures. The system consists of a Master Console, from which an operator can control the system, and a Slave Robot, which moves in accordance with the instructions dictated by the Master Console. The operative field can be viewed through a camera which is attached to the flexible ureteroscope by the physician on the video display. Any commercially available, 510(k) cleared, holmium YAG type surgical laser device, any legally marketed laser fiber with the size between 200µm and 365µm, and select 510(k) cleared flexible ureteroscopes and urethral access sheaths as outlined below can be used with Zamenix™ P.

- Compatible flexible ureteroscopes:
  - Lithovue™ (Boston Scientific, K153049)
- Compatible Ureteral Access Sheath:
  - Navigator™ (Boston Scientific, K122649)

The Zamenix™ P system provides an ergonomic surgical posture and includes manipulation methods allowing for precise control of endoscopes and surgical tools. The system includes a respiration synchronization function that synchronizes ureteroscope movement with the patients breathing to provide aim assistance during stone collection and lasering, maximizing laser hit rate during fragmentation, and minimizing the risk of mucosal injury. The system also includes a stone size guide that assists users in determining if additional stone lasering is required to ensure the stone / stone fragment will fit through the ureteral access sheath during basketing. Finally, the Zamenix™ P also streamlines repeated approaches through an automatic driving function.

The Zamenix™ P consists of the following components:

- Zamenix™ P Master Console
- Zamenix™ P Slave Robot
- Zamenix™ P Software
- Supporting Device Specific Accessories
    - Laser Fiber Holder
    - Drape Assembly
    - Zamenix™ Urobasket ZT

Summary descriptions of each component are outlined below:

- **Zamenix™ P Master Console:** The Zamenix™ P Master Console contains the primary procedural display interface for the physician that is provided by a touchscreen monitor for physician viewing and computers running the Zamenix™ P software. The monitor has a touchscreen and allows for user input during setup and intra-operative use. The Zamenix™ P Master Console also contains multiple user interfaces that enable the user to control the flexible ureteroscope and surgical instruments using a combination of foot pedals, handles / gimbals, and rotational wheels. Users can adjust the position of components to their preference so that they can perform the procedure in a user-friendly and comfortable posture.
- **Zamenix™ P Slave Robot:** The Zamenix™ P Slave Robot is the operating component of the Zamenix™ P. From the Zamenix™ P Master Console, the user can remotely control the flexible ureteroscope and surgical instruments (laser fiber or stone retrieval basket) which are mounted on the Zamenix™ P Slave Robot.
- **Zamenix™ P Software:** The Zamenix™ P Software controls the Zamenix™ P Master Console and Zamenix™ P Slave Robot and provides the user with the ability to safely control compatible flexible ureteroscopes around the interior of the kidney. It receives user input from the Zamenix™ P Master Console, computes the appropriate robotic motion to coordinate the movement of the Zamenix™ P Slave Robot. It provides a graphical user interface where the endoscopic camera view is shown in real time and displays important system status information.

Device specific instruments and accessories for the Zamenix™ P are outlined below. All devices are single-use devices and sterilized via EO.

- **Laser Fiber Holder:** The Laser Fiber Holder is a surgical tool mounted on the Zamenix™ P Slave Robot. It is designed for use in fixing a compatible FDA-cleared laser fiber between 200µm through 365µm in diameter to the required length during use. During use, the laser fiber is passed through the Laser Fiber Holder, after which it is fed into the ureteroscope channel to the desired working length. A thumb screw on the Laser Fiber Holder firmly anchors the laser fiber to the desired length.
- **Drape Assembly:** The Drape Assembly is a sterile cover designed to maintain the sterility of the Zamenix™ P Slave Robot during surgery.
- **Zamenix™ Urobasket ZT:** The Zamenix™ Urobasket ZT is a surgical tool mounted on the Slave Robot. It is designed to grasp and remove stones and foreign substances after entering the urinary tract through the channel of the flexible ureteroscope. While primarily intended for control by the user via the Zamenix™ P Master Console, it also includes a knob and two trigger blocks that allow the physician to perform manual adjustments as needed to support the procedure.

## Indications for Use

The Zamenix™ P is indicated for endoscopic examination in the urinary tract with transurethral access and can be used to examine the interior of the kidney and using additional accessories, to perform various diagnostic and therapeutic procedures. The device is intended for use in patients aged 22 or older.

## Technological Characteristics

The subject and predicate devices include similar technological characteristics:

- Both the subject and predicate device systems are used to access and visualize anatomical locations inside the urinary tract and kidney with endoscopic devices to perform various diagnostic and therapeutic procedures in the urinary system.
- Both systems include a control console (Master Console) and manipulator unit (Slave Robot) with controlling software.
    - Both system's control consoles include a touchscreen interface with multiple mechanisms for controlling movement of the manipulator unit.
    - Both system's manipulator units are compatible with third party flexible ureteroscopes.
    - Both system's software units function to provide a graphical user interface for the system and interpret, manage, and communicate user inputs between system components.

- Both systems also include supporting endourology instruments and accessories to support use of the device including drape systems and laser fiber holders.
    - The subject device laser fiber holder is substantially equivalent to the laser fiber holder of the predicate device. Both accessories are intended to house and introduce a laser fiber during endoscopic surgical procedures. Both components are compatible with a range of laser fiber diameters and include a screw mechanism for anchoring the fiber in place during use. Both components are provided sterile for single use.
    - The subject device drape assembly is substantially equivalent to the predicate device. Both components are intended to create a sterile barrier between non-sterile components and the rest of the sterile field to prevent contamination during various procedures. Both components are manufactured out of similar materials as the reference device. Both components are provided sterile for single use.

The following technological differences exist between the subject and predicate devices. Any minor technological differences noted are mitigated by comparison to the reference device and by supporting performance testing and do not raise different questions of safety or effectiveness.

- The subject and predicate device robotic systems include minor differences in the software interface and control mechanisms. The subject device includes several software features which are not available on the predicate device.
- The subject and predicate device robotic systems include minor differences in the component range of motion and system accuracy. Any differences do not impact the ability of the device to perform its intended use in the intended patient population.
- The subject and predicate device robotic systems are compatible with different flexible ureteroscopes.
- The subject device includes a device-specific basketing component which was not provided with the predicate device. The predicate device is compatible with any legally marketed basketing components. K170898 is included as a reference device to support the identified differences and performance of the subject device.
- The subject and predicate device laser fiber holders include minor differences in materials and dimensions.
- The subject and predicate device drape assemblies include minor differences in materials and dimensions. K200238 is included as a reference device to support the identified differences.

**Non-Clinical Performance Testing Summary**

The following performance data was provided to support substantial equivalence:

- Sterilization Validation per ISO 11135 (Zamenix™ single use accessories)
- Shelf-Life Performance Testing (Zamenix™ single use accessories)

- Biocompatibility testing in accordance with ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-11, ISO 10993-23 (Zamenix™ Urobasket ZT)
- Biocompatibility testing in accordance with ISO 10993-5, ISO 10993-10, ISO 10993-23 (Drapes and Laser Fiber Holder)
- Viral penetration testing per ASTM F1671 (Zamenix™ Drape Assembly)
- Electrical Safety and Electromagnetic Compatibility Testing per IEC 60601-1, IEC 60601-1-2, IEC 60601-4-2, IEC 80601-2-77, IEC 60601-1-6
- System and component level design verification testing
- Software testing and documentation in accordance with FDA Guidance "Content of Premarket Submissions for Device Software Functions" and "Off-The-Shelf Software Use in Medical Devices"
- Cybersecurity testing and documentation in accordance with FDA Guidance "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions"
- Human factors testing in accordance with FDA guidance "Applying Human Factors and Usability Engineering to Medical Devices"

A comparative design validation study against existing manual techniques was also conducted to evaluate the effectiveness of the proposed device under simulated use conditions for a retrograde intrarenal surgery (RIRS) with lithotripsy and stone removal case in a live porcine model. All data collected demonstrated that the proposed device performed in conformance with its intended use with equivalent results to existing manual techniques and that the intended users were able to perform the procedure as intended.

**Conclusion**

Based on the similarities of the intended use/indications for use, technological and functional characteristics, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.