May 22, 2025

Urotronic, Inc.
Alex Zuniga
Director of Regulatory Affairs
2495 Xenium Lane N
Minneapolis, Minnesota 55441

Re: K250910
Trade/Device Name: Optilume® High Pressure Urological Balloon Dilation Catheter
Regulation Number: 21 CFR 876.5470
Regulation Name: Ureteral Dilator
Regulatory Class: II
Product Code: EZN
Dated: March 25, 2025
Received: March 26, 2025

Dear Alex Zuniga:

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,

Jessica K. Nguyen -S

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250910

Please provide the device trade name(s).

Optilume® High Pressure Urological Balloon Dilation Catheter

Please provide your Indications for Use below.

The Optilume® High Pressure Urological Balloon Dilation Catheter is indicated for dilation of the urinary tract.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

I. SUBMITTER

510(K) Owner's Name: Urotronic Inc

Legal Manufacturer Address: 2495 Xenium Lane N, Minneapolis, MN 55441

Phone/Fax/Email : Phone : (763) 439-6293
Email: azuniga@laborie.com

Name of Contact Person: Alex Zuniga
Director of Regulatory Affairs

Address/Contact: 2495 Xenium Lane N
Minneapolis, MN 55411

Date Prepared: May 22, 2025

II. DEVICE

Trade or Proprietary Name: Optilume® High Pressure Urological Balloon Dilation Catheter

Common or Usual Name: Ureteral Balloon Dilatation Catheter

Classification Name: Dilator, Catheter, Ureteral
(21 CFR section 876.5470)
Product Code: EZN Device
Class: 2

Dilator, Urethral
(21 CFR section 876.5520)
Product Code: KOE
Device Class: 2

III. PREDICATE DEVICE

The Optilume® High Pressure Urological Balloon Dilation Catheter is substantially equivalent in performance, indication, design and materials to Uromax Ultra™ High Pressure Balloon Dilatation Catheter, cleared under premarket notification number K130804.

This predicate has not been subject to a design-related recall. No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Optilume® High Pressure Urological Balloon Dilation Catheter is an 0.038" (0.97mm) guidewire and flexible cystoscope compatible over-the-wire (OTW) catheter with a dual lumen design with a tapered atraumatic tip. The Optilume® High Pressure Urological Balloon Dilation Catheter is used to exert radial force to dilate narrow urinary tract segments (strictures). The distal end of the catheter is a non-compliant inflatable balloon. The 75 cm long Optilume® High Pressure Urological Balloon Dilation Catheter is supplied in five balloon diameters ranging from 4-10mm and balloon lengths ranging from 20-80mm. The balloon catheter is supplied sterile for single use.

Target population

The Optilume® High Pressure Urological Balloon Dilation Catheter is designed to be used on patients requiring dilation of urethral or ureteric strictures.

Duration of Use

Optilume® High Pressure Urological Balloon Dilation Catheter is intended for transient use (less than 1 hour).

Intended User Profile

The Optilume® High Pressure Urological Balloon Dilation Catheter is intended for use by physicians with thorough understanding of techniques, clinical applications and risks of balloon catheter dilation in the urinary tract before using this product.

V. INDICATIONS FOR USE

The Optilume® High Pressure Urological Balloon Dilation Catheter is indicated for the dilation of urinary tract.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Optilume® High Pressure Urological Balloon Dilation Catheter is substantially equivalent in performance, indication, design and materials to Boston Scientific Uromax Ultra™ Balloon Dilatation Catheter, cleared under premarket notification number K130804. There are no significant technological differences between the subject device and the predicate. Both the subject and predicate devices have dual lumens to allow for .038" guidewire and for balloon inflation. The rated burst

inflation pressure is 20 atm for both devices. The Optilume® High Pressure Urological Balloon Dilation Catheter diameters and lengths (4–10 mm diameter and 20-80mm long) fall within the range covered in the Uromax Ultra™ Balloon Dilatation Catheter (4-10 mm diameter and 40 – 100 mm long). Both devices are 75 cm long, supplied sterile, and intended for a single use.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The biocompatibility evaluation for the Optilume® High Pressure Urological Balloon Dilation Catheter device was conducted in accordance with ISO 10993-1 and FDA guidance document for Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process". The Optilume® High Pressure Urological Balloon Dilation Catheter are categorized as a limited duration (≤ 24-hour) device contacting breached or compromised surfaces

The series of biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic toxicity
- Materials-Mediated Pyrogen

The biocompatibility testing and passing results demonstrate that the Optilume® High Pressure Urological Balloon Dilation Catheter meets the biocompatibility requirements of the device based on its classification and intended use.

Performance Testing

Performance testing was conducted with samples before and after accelerated aging. The series of performance testing included the following tests:

- Balloon testing
    - Balloon Diameter
    - Balloon Length
    - Balloon Inflation / Deflation Time
    - Balloon Fatigue Testing
    - Balloon Burst Testing
    - Balloon Compliance

- Dimensional Testing
  - Stricture Entry Profile
  - Catheter Profile
  - Catheter Working Length
  - Markerband to Markerband Spacing
  - Markerband to Distal Cone Distance
- Simulated Use - catheter preparation, deployment, and retraction including trackability
- Radiopacity
- Tensile strength testing
  - Proximal Balloon Bond
  - Distal Balloon Bond
  - Hub to shaft
  - Inner shaft to Multilumen
- Guidewire compatibility
- High Pressure Test
  - Nominal burst pressure
  - Rated Burst pressure
  - Burst mode (radial vs. Longitudinal)
  - Freedom From Leakage
- Cystoscope compatibility

The results of the performance testing demonstrate equivalence of the Optilume® High Pressure Urological Balloon Dilation Catheter to the predicate device. The subject device was tested to meet design requirements similar to the predicate. All testing passed, demonstrating that the Optilume® High Pressure Urological Balloon Dilation Catheter is substantially equivalent to the legally marketed predicate device.

Sterilization

The Optilume® High Pressure Urological Balloon Dilation Catheter are sterilized using ethylene oxide in a validated cycle demonstrating a sterility assurance level of 10^{-6}. EO sterilization validation was conducted in conformance with ISO 11135:2014, Sterilization of health care products - Ethylene oxide - Requirements for development, validation, and routine control of a sterilization process for medical devices; which is the FDA-recognized standard for industrial EO sterilization. The EO sterilization cycle qualification was conducted using the overkill approach in conformance with ISO 11135-1:2014, Annex B; Conservative determination of lethal rate of the sterilization Process-Overkill approach.

Packaging and Distribution

The Optilume® High Pressure Urological Balloon Dilation Catheter was subjected to distribution testing, environmental conditioning and verification testing to demonstrate that the product and package would be undamaged throughout the product life and maintain the device sterility.

No animal studies or clinical testing was provided to support substantial equivalence between the subject and predicate devices.

VIII. CONCLUSIONS

The Optilume® High-Pressure Urological Balloon Dilation Catheter is substantially equivalent to the UroMax Ultra™ High-Pressure Balloon Catheter (K130804) based on test data provided, the same indication for use, biocompatibility and similar technological characteristics.