January 2, 2020

Urotronic Inc
℅ Ms. Ming Cheng Chew
Regulatory Consultant
Libra Medical Inc.
8401 73rd Ave N. Suite 63
Minneapolis, MN 55428

Re: K191061
Trade/Device Name: Optilume Basic Urological Balloon Dilation Catheter
Regulation Number: 21 CFR 876.5520
Regulation Name: Urethral Dilator
Regulatory Class: Class II
Product Code: KOE
Dated: November 22, 2019
Received: November 25, 2019

Dear Ms. Chew:

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,

Jessica K. Nguyen, Ph.D.
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecological and Urological 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191061

Device Name

Optilume Basic Urological Balloon Dilation Catheter

Indications for Use *(Describe)*

The Optilume Basic Urological Balloon Dilation Catheter is indicated for the dilation of urethral strictures.

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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1.0 510(K) SUMMARY

1.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: 12/31/19

1.1.1 CONTACT INFORMATION

Submitter/Manufacturer	**Urotronic Inc** 2495 Xenium Lane N. Minneapolis MN 55441 Tel:763-670-5247 Fax: 763-477-6357
Primary Submission Contact	Ming Cheng Chew Regulatory Consultant, Libra Medical, Inc. 8401 73rd Ave North, Suite 63 Brooklyn Park, MN 55428 Tel: 763-232-3701 Email: mcchew@libramed.com
Secondary Submission Contact	Sew-Wah Tay Regulatory Consultant, Libra Medical, Inc. 8401 73rd Ave North, Suite 63 Brooklyn Park, MN 55428 Tel: 612-801-6782 Email: swtay@libramed.com

1.1.2 DEVICE INFORMATION

Trade Name	Optilume Basic Urological Balloon Dilation Catheter
Common Name	Dilator, Urethral
Classification Name	Urethral Dilator
Regulation Number(s):	876.5520
Class	II
Classification Panel	Gastroenterology/Urology
Product Code	KOE
Previous Submission	none

There are no previous submission for the subject device.

1.2 PREDICATE DEVICE

Boston Scientific UroMAX Ultra Balloon Dilatation Catheter (K130804)

1.3 DEVICE DESCRIPTION OVERVIEW

The Optilume Basic Urological Balloon Dilation Catheter (Optilume Basic) is a 0.038" (0.97 mm) guidewire and flexible cystoscope compatible over-the-wire (OTW) catheter with a dual lumen design with a tapered atraumatic tip. The Optilume Basic is used to exert radial force to dilate narrow urethral segments (strictures). The distal end of the catheter is a semi-compliant inflatable balloon. The usable length is 75 cm and allows the device to be compatible with the working channel of a standard flexible cystoscope. The device has two radiopaque marker bands that indicate the working length of the balloon.

The device is sterilized using ethylene oxide in a Tyvek pouch. Post sterilization the pouched catheter is sealed in a foil pouch with desiccant and contained within a single unit carton.

1.4 INTENDED USE

The Optilume Basic Urological Balloon Dilation Catheter is intended for the dilation of the urinary tract.

1.5 INDICATION FOR USE

The Optilume Basic Urological Balloon Dilation Catheter is indicated for the dilation of urethral strictures.

1.6 PERFORMANCE DATA OVERVIEW

The Optilume Basic Urological Balloon Dilation Catheter underwent extensive testing including:

- Dimensional
- Balloon Burst
- Leakage Testing
- Kink Resistance
- Guidewire, Luer, and Cystoscope Compatibility
- Trackability
- Tensile Testing
- Fatigue Testing
- Balloon Compliance Testing
- Biocompatibility Testing – Cytotoxicity, Sensitization, Irritation, Systemic Toxicity
- Packaging Testing – seal strength, bubble leak, distribution
- Accelerated aging

A GLP animal study was performed in canines to evaluate the safety and use of the device. The device performed as intended and no device-related adverse events occurred.

1.7 SUBSTANTIAL EQUIVALENCE

The Optilume Basic Urological Balloon Dilation Catheter is substantially equivalent to the UroMax device (K130804). It has the same intended use for the dilation of the urinary tract. The test data showed that the technological difference between the Optilume Basic Urological Balloon Dilation Catheter and its predicate do not raise safety and efficacy issues.

Table 1-1: Device Comparison to the Predicate Device

Characteristic	Optilume Basic	Uromax Ultra Balloon Catheter
Intended Use	Intended for the dilatation of the urinary tract.	Same
Indication for Use	The Optilume Basic Urological Balloon Dilation Catheter is indicated for the dilation of urethral strictures.	Uromax Ultra TM Balloon Dilatation Catheters are recommended for dilatation of the urinary tract.
Catheter usable length	75 cm	Same
Balloon diameters	6 mm, 8 mm, 10 mm,	4mm, 5mm, 6mm, 7 mm, 8mm, 10 mm
Balloon lengths	30 mm, 50 mm	40 mm, 60 mm, 80 mm, 100 mm
Rated burst pressure	10 atm, 12 atm	20 atm
Guidewire compatible	0.038" (0.9652 mm)	Same
Biocompatibility compliance	ISO 10993-1 for mucosal tissue	Same
Delivery of catheter to treatment site	Insert into the working channel of a cystoscope.	Same
Visualization during placement	Cystoscope and/or fluoroscopy – radiopaque marker bands	Same
Sterilization	EO, one-time use, SAL 10^{-6}	Same
Inflation fluid	Saline/contrast	Same

1.8 CONCLUSION

Based on the test data and the same intended use, the Optilume Basic Urological Balloon Dilation Catheter is found to be substantially equivalent to its predicate.