June 30, 2023

Urotronic, Inc.
% Gabriela Molnar, M.S.
Regulatory Consultant
Libra Medical, Inc.
8401 73rd Avenue North, Suite 63
Minneapolis, MN 55428

Re: P220029
Trade/Device Name: Optilume™ BPH Catheter System
Product Code: QXB
Filed: December 12, 2022
Amended: April 7, 2023

Dear Gabriela Molnar:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Optilume™ BPH Catheter System. This device is indicated for the treatment of obstructive urinary symptoms associated with Benign Prostatic Hyperplasia (BPH) in men ≥ 50 years of age. We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions of approval described below. Although this letter refers to your product as a device, please be aware that some approved products may instead be combination products. The Premarket Approval Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm identifies combination product submissions.

The sale and distribution of this device are restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (the act). FDA has determined that these restrictions on sale and distribution are necessary to provide reasonable assurance of the safety and effectiveness of the device. Your device is therefore a restricted device subject to the requirements in sections 502(q) and (r) of the act, in addition to the many other FDA requirements governing the manufacture, distribution, and marketing of devices.

Expiration dating for this device has been established and approved for 12 months for the Optilume BPH DCB Catheter and 2 years for the Pre-dilation Catheter. This is to advise you that the protocol you used to establish this expiration dating is considered an approved protocol for the purpose of extending the expiration dating as provided by 21 CFR 814.39(a)(7).

Continued approval of the PMA is contingent upon the submission of periodic reports, required under 21 CFR 814.84, at intervals of one year (unless otherwise specified) from the date of approval of the original PMA. This report, identified as "Annual Report" and bearing the applicable PMA reference number, should be submitted to the address below. The Annual Report should indicate the beginning and ending date of the period covered by the report and should include the information required by 21 CFR 814.84.

In addition to the above, and in order to provide continued reasonable assurance of the safety and effectiveness of the PMA device, the Annual Report must include, separately for each model number (if applicable), the number of devices sold and distributed during the reporting period, including those distributed to distributors. The distribution data will serve as a denominator and provide necessary context for FDA to ascertain the frequency and prevalence of adverse events, as FDA evaluates the continued safety and effectiveness of the device.

You must obtain approval of your post-approval study (PAS) protocol(s) within 60 days from the date of this order. Within 30 days of your receipt of this letter, you must submit a PMA supplement that includes a complete protocol of your post-approval study described below. Your PMA supplement should be clearly labeled as a "PMA Post-Approval Study Protocol" as noted below and submitted to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

In addition to the Annual Report requirements, you must provide the following data in post-approval study (PAS) reports for each PAS listed below. Your PMA supplements should be clearly labeled as a "PMA Post-Approval Study Protocol" as noted below and submitted to the address below. Please reference the PMA number above to facilitate processing. If there are multiple protocols being finalized after PMA approval, please submit each protocol as a separate PMA supplement.

1. The PINNACLE study (PR1087 version J provided in P220029 original submission) is designed to conduct follow-up at Foley removal, 14-, 30-days, 3-, 6-, and 12-months post-procedure, and to continue the follow-up annually thereafter through 5 years. It is intended to verify the continued safety and effectiveness of the Optilume BPH Catheter System after 12-months follow-up for the subjects who received the Optilume BPH Catheter System in the PINNACLE study. Each patient's follow-up will be continued out to 5 years post-treatment. Study reports will continue to be generated and written in accordance with the endpoint definitions specified in the PINNACLE Statistical Analysis Plan for the randomized, crossover, and pharmacokinetics (PK) cohorts. The endpoints are as follows:

    a. responder analyses with a responder defined as International Prostate Symptom Score (IPSS) improvement of 35%, 40%, and 50%,

    b. change in post-void residual (PVR) urine volume,

    c. change in sexual function (International Index of Erectile Function (IIEF), Male Sexual Health Questionnaire – Ejaculatory Dysfunction (MSHQ-EjD),

    d. change in BPH impact index (BPH-II),

e. change in quality of life (EQ-5D)

f. change in pain score,

g. change in peak urinary flow (Qmax),

h. proportion of subjects experiencing a return to 'normal' symptom severity (IPSS<8)), and

i. frequency and severity of all adverse events (AEs),

For any subjects with available data at 12 months, you should provide change in semen quality characteristics and semen paclitaxel PK.
Progress reports will be submitted to the FDA annually after PMA approval.

2. The PEAK (Safety and Effectiveness of the Optilume BPH Catheter System in a Post-market Study) post approval study (PR1309, received in a June 8, 2023 email) is a prospective, single arm, multi-center, post market clinical trial evaluating the continued safety and effectiveness of the Optilume BPH Catheter System. This PAS includes a semen sub-study evaluating semen quality and paclitaxel pharmacokinetics (PK) in a subset of subjects. The study will enroll up to 92 subjects at up to 15 sites in the United States and at least 34 of the enrolled subjects will be evaluated for semen quality and PK. The study will be open to men 50 years of age or older who meet the selection criteria. Clinical follow-up wil be conducted at 1-, 3-, 6-, and 12-months post-procedure, and annually thereafter through 5 years. For subjects enrolled in the semen sub-study, semen PK samples will be collected at 6 months and 12 months. Samples collection will continue periodically (every 3 months) thereafter until paclitaxel is no longer detectable (i.e., below the limit of quantitation). In addition, semen quality will be assessed at baseline, 3 months, 6 months, and 12 months. The primary effectiveness endpoint is improvement in the International Prostate Symptom Score (IPSS) at 12 months. The mean percent reduction in IPSS at 12 months will be compared to a performance goal of 30%. Ancillary endpoints include improvement in IPSS, improvement in international continence society (ICS) male short form (SF), improvement in Qmax (fastest flow rate), and improvement in post-void residual volume (PVR) at each follow-up, and freedom from repeat intervention. The primary safety endpoint is freedom from composite treatment related serious adverse events (SAEs) (device-related rectal fistula or gastrointestinal (GI) fistula, device-related formilation of fistula between the rectum and urethra, device-related new onset severe urinary retention lasting >14 consecutive days post-healing, device-related unresolved new onset stress urinary incontinence by 90 days, device-related bleeding requiring transfusion, and device-related urethra or prostatic capsule rupture requiring surgical intervention). The secondary safety endpoint is average change in sperm concentration from baseline to 3 months. The ancillary safety endpoints include frequency and severity of all adverse events (AEs), change in semen quality characteristics from baseline over time (semen sub-study only), and semen paclitaxel PK (semen sub-study only).

For the continued follow-up of the PINNACLE study, you must submit separate PAS Progress Reports, every six (6) months for the first two (years) and annually thereafter, unless otherwise specified by FDA.

Please note that labeling should be updated on a yearly basis, after each yearly interval of follow up is completed for each PAS.

From the date of study protocol approval, you must meet the following timelines for the PEAK PAS:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months

In addition, you must submit separate periodic reports on the progress of the PEAK PAS as follows:

- PAS Progress Reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the PMA approval letter, unless otherwise specified by FDA.
- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports every 3 months in addition to your periodic (6-month) PAS Progress Reports, until FDA notifies you otherwise.
- Submit the Final PAS Report three (3) months from study completion (i.e., last subject's last follow-up date).

Each PAS report should be submitted to the address below identified as a "PMA Post-Approval Study Report" in accordance with how the study is identified above and bearing the applicable PMA reference number.

Be advised that failure to comply with any post-approval requirement, including initiation, enrollment, and completion requirements outlined above, constitutes grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.82(c) and 814.46(a)(2).

Be advised that the failure to conduct any such study in compliance with the good clinical laboratory practices in 21 CFR part 58 (if a non-clinical study subject to part 58) or the institutional review board regulations in 21 CFR part 56 and the informed consent regulations in 21 CFR part 50 (if a clinical study involving human subjects) may be grounds for FDA withdrawal of approval of the PMA in accordance with 21 CFR 814.46(a)(3)-(4).

Be advised that protocol information, interim and final results will be published on the Post-Approval Studies Program Database Webpage https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

In addition, the results from any post approval study should be included in the labeling as these data become available. Any updated labeling must be submitted to FDA in the form of a PMA Supplement. For more information on post-approval studies, see the FDA guidance document entitled, "Procedures for Handling Post-Approval Studies Imposed by Premarket Approval Application Order" (https://www.fda.gov/media/71327/download).

This is a reminder that as of September 24, 2014, class III devices are subject to certain provisions of the final Unique Device Identification (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, 21 CFR 814.84 (b)(4) requires PMA annual reports submitted after September 24, 2014, to identify each device identifier currently in use for the subject device, and the device identifiers for devices that have been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013. Combination Products may also be subject to UDI requirements (see 21 CFR 801.30). For more information on these requirements, please see the UDI website, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-udi-system.

Before making any change affecting the safety or effectiveness of the PMA device, you must submit a PMA supplement or an alternate submission (30-day notice) in accordance with 21 CFR 814.39. All PMA supplements and alternate submissions (30-day notice) must comply with the applicable requirements in 21 CFR 814.39. For more information, please refer to the FDA guidance document entitled, "Modifications to Devices Subject to Premarket Approval (PMA) - The PMA Supplement Decision-Making Process" https://www.fda.gov/media/81431/download.

You are reminded that many FDA requirements govern the manufacture, distribution, and marketing of devices. For example, in accordance with the Medical Device Reporting (MDR) regulation, 21 CFR 803.50 and 21 CFR 803.52 for devices or post-marketing safety reporting (21 CFR 4, Subpart B) for combination products, you are required to report adverse events for this device. Manufacturers of medical devices, including in vitro diagnostic devices, are required to report to FDA no later than 30 calendar days after the day they receive or otherwise becomes aware of information, from any source, that reasonably suggests that one of their marketed devices:

1. May have caused or contributed to a death or serious injury; or

2. Has malfunctioned and such device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

Additional information on MDR, including how, when, and where to report, is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems and on combination product post-marketing safety reporting is available at (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products).

In accordance with the recall requirements specified in 21 CFR 806.10 for devices or the post-marketing safety reporting requirements (21 CFR 4, Subpart B) for combination products, you are required to submit a written report to FDA of any correction or removal of this device initiated by you to: (1) reduce a risk to health posed by the device; or (2) remedy a violation of the act caused by the device which may present a risk to health, with certain exceptions specified in 21 CFR 806.10(a)(2). Additional information on recalls is available at https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/industry-guidance-recalls.

CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading. CDRH will notify the public of its decision to approve your PMA by making available, among other information, a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet Home Page located at https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals. Written requests for this information can also be made to the Food and Drug Administration, Dockets Management Branch, (HFA-305), 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by submitting a petition for review under section 515(g) of the act and requesting either a hearing or review by an independent advisory committee. FDA may, for good cause, extend this 30-day filing period.
Failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of approval is a violation of law.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with a copy of all final labeling. Final labeling that is identical to the labeling approved in draft form will not routinely be reviewed by FDA staff when accompanied by a cover letter stating that the final labeling is identical to the labeling approved in draft form. If the final labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

If you have any questions concerning this approval order, please contact Bonhye Koo, Ph.D. at (301) 796-2435 or Bonhye.Koo@fda.hhs.gov.

Sincerely,

Sharon M. Andrews -S

Sharon M. Andrews
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