June 29, 2023

Flume Catheter Company, Ltd.
% Elaine Duncan
President
Paladin Medical, Inc.
P.O. Box 560
Stillwater, MN 55082

Re: K231101
Trade/Device Name: FLUME catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL, KOB
Dated: May 26, 2023
Received: May 30, 2023

Dear Elaine Duncan:

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 -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

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)*

K231101

Device Name
FLUME catheter

Indications for Use *(Describe)*
The FLUME catheter is intended for bladder drainage via urethral or suprapubic route.

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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SPECIAL 510(k) SUMMARY

Submitted on behalf of: **The Flume Catheter Company Ltd.**
Company Contact Name: Roger Holmes

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by: Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
Telephone: 715-549-6035

SUBMISSION CONTACT PERSON: Elaine Duncan, MSME, RAC, FAIMBE
President, Paladin Medical, Inc.

DATE PREPARED: **June 28, 2023**
TRADE NAME: FLUME catheter
COMMON NAME: Catheter, Retention Type, Balloon & Suprapubic
REGULATION NAME: Urological Catheter and Accessories
REGULATION NUMBER: 876.5130
REGULATORY CLASS: II
PRODUCT CODE: EZL, KOB

PREDICATE DEVICE:
FLUME catheter K212151. The predicate device has not been subject to a design-related recall.

DESCRIPTION of the DEVICE:
The **FLUME catheter** is intended for the drainage of urine from the bladder. The FLUME catheter is a sterile indwelling urinary catheter intended for single use. The FLUME catheter is made using polyurethane-based polymers. The catheter has an inflatable retention balloon attached to the catheter shaft. The catheter has a dual lumen tube. The larger lumen is for urine drainage. The smaller lumen is used to inflate and deflate the balloon with sterile water. The distal end has two opposite eye holes, which are used for drainage. The product is available in standard sizes. The catheter may be placed following the institutions' standard practice for either urethral bladder drainage or via percutaneous suprapubic access to the bladder.

INDICATIONS FOR USE:
The FLUME catheter is intended for bladder drainage via urethral or suprapubic route.

SUBSTANTIALLY EQUIVALENT TO:
The **FLUME** catheter is substantially equivalent to FLUME catheter, K212151. There are no changes or differences made to the FLUME catheter to extend the indication for use to include suprapubic drainage. The only change in this Special 510(k) is to the current indication for use and instructions for use. According to the risk assessment, there is no difference to the risk to the patient when the FLUME catheter is placed suprapubic.

SUMMARY of NON_CLINICAL TESTING:
- Biocompatibility testing from the predicate device was leveraged for the subject device since the materials and method of manufacture are identical. The biocompatibility testing endpoints completed for the predicate device align with the biocompatibility evaluation expectations to support suprapubic use. Biocompatibility was conducted per International Standard ISO 10993-1, "Biological Evaluation of medical devices – Part 1: Evaluation and Testing within a risk management process:
    - Cytotoxicity,
    - Sensitization,
    - Irritation,
    - Acute Systemic Toxicity,
    - Subacute Systemic Toxicity,
    - Material Mediated Pyrogenicity

  - Subcutaneous Implantation,
  - Genotoxicity.

- Bacterial endotoxin testing (BET) was conducted to ensure the device meets pyrogen limit specifications.

CONCLUSION: The FLUME catheter is substantially equivalent to the predicate device.