November 3, 2021

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

Re: K212151
Trade/Device Name: FLUME catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: September 29, 2021
Received: September 30, 2021

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, 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)*

K212151

Device Name
FLUME catheter

Indications for Use *(Describe)*
The FLUME catheter is intended for the drainage of the urinary tract.

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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510(K) SUMMARY
FLUME catheter

Submitted on behalf of:

Company Name: The Flume Catheter Company Ltd.
Contact Name: Roger Holmes

Address: The Granary, Mill House
Frensham, Farnham, GU10 3EE,
United Kingdom
Telephone: 44(0) 207 808 9125

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

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

DATE PREPARED: **November 3, 2021**
TRADE NAME: FLUME catheter
COMMON NAME: Catheter, Retention Type, Balloon
REGULATION NAME: Urological Catheter and Accessories
REGULATION NUMBER: 876.5130
REGULATORY CLASS: II
PRODUCT CODE: EZL

PREDICATE DEVICE:
Teleflex Rusch All-Silicone Foley Catheter (K980870)

DESCRIPTION of the DEVICE:
The **FLUME catheter** is intended for the drainage of the urinary tract. 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 draining urine from the urinary tract. 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 size 14 Fr with a smooth shaft.

INDICATIONS FOR USE:
The FLUME catheter is intended for the drainage of the urinary tract.

SUBSTANTIALLY EQUIVALENT TO:
The **FLUME** catheter is substantially equivalent to Teleflex Rusch All-Silicone Foley Catheter **K980870.**

510(K) SUMMARY
FLUME catheter

Comparison of Technological Characteristics with Predicate Device

Attribute	Rusch Silicone Foley Catheter	**FLUME** catheter	Similarities and Differences
Classification Name	Catheter, Retention Type, Balloon	Catheter, RetentionType, Balloon	SAME
Produce Code	EZL	EZL	SAME
Regulation Number	876.5130	876.5130	SAME
Class	2	2	SAME
Indication for Use	The Rusch Silicone Foley is used to drain fluids to and from the urinary tract	The FLUME catheter is intended for the drainage of the urinary tract	FLUME catheter is only offered as a two-lumen catheter, drainage only
Intended Population	Male or female	Male or female	SAME
Lumen	Two-way: lumen to fill balloon, lumen to drain bladder.	Two-way: lumen to fill balloon, lumen to drain bladder	SAME
Indwelling Time	Maximum indwell time of 29 days	Maximum indwell time of 29 days	SAME
Single use or reusable	Single use	Single use	SAME
Size Ranges	Shaft sizes 8Fr to 26Fr, Net effective length 285mm for the standard Teleflex Rusch.	Shaft size 14Fr, i.e.,outer diameter of 4.7mm. Net effective length of 315mm.	The difference in length does not affect the safety and effectiveness compared to the predicate device.
Balloon Volume	$5cm^3$	$5cm^3$	SAME
Balloon positioning	Below/proximal of the catheter tip and drain holes	Envelops catheter tip and positioned lateral to drain holes.	The FLUME balloon is positioned so that it envelops the tip at the time of inflation, cushioning the bladder wall on emptying and aids full drainage of the bladder.
Balloon attachment	Bonded to catheter shaft, around full circumference of both ends of the balloon component	Bonded to cathetershaft for half the circumference of both ends of the balloon component	Testing shows differences do not affect safety and effectiveness compared to the predicate device.
Sold Sterile and Method	Ethylene Oxide 10^{-6} SAL	Gamma; ISO 11137-2; 10^{-6} SAL	Met requirements
Biocompatibility/materials	Silicone	ISO 10993; polyurethanes	Materials differences do not introduce new risks, meets ISO 10993
Tip shape	Rounded, tapered	Rounded, tapered	SAME
Drain holes	Two opposite eyeholes at distal end	Two opposite eyeholes at distal end	SAME
Drainage connector	Funnel	Funnel	SAME
Check valve	Luer activated valve	Luer activated valve	SAME

SUMMARY of NON_CLINICAL TESTING:

- 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.

- Sterilization validation was conducted per the following FDA-recognized standards:
    - ISO 11137-1:2006/(R)2015, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.
    - ISO 11137-2:2013, Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose

- Transportation simulation, package integrity and shelf-life were conducted to demonstrate that the subject device packaging materials can withstand the rigors of shipping and distribution and maintain the integrity of the sterile barrier during transportation and its proposed shelf life. Accelerated aging was performed in conformance with ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

- Performance/Functional testing was conducted per ASTM F623-19 Standard Performance Specification for Foley Catheter.

CONCLUSION: The non-clinical testing provided support that the FLUME catheter is substantially equivalent to the predicate device.