September 21, 2018

Pathway, LLC
David Stroup
Managing Partner
8779 Cottonwood Avenue, Suite 105
Santee, CA 92071

Re: K181616
Trade/Device Name: PSM 3-Way Silicone Foley Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: August 20, 2018
Received: August 21, 2018

Dear David Stroup:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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)*
K181616

Device Name
PSM 3-Way Silicone Foley Catheter

Indications for Use *(Describe)*
Urological catheter intended for drainage/irrigation of the urinary tract. Catheterization is accomplished through the urinary tract, but also suprapubic placement or by nephrostomy. Intended population is adults and pediatrics.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY – K181616

Submitter Information

Company Name:	Pathway, LLC.
Company Address:	8779 Cottonwood Avenue, Suite 105 Santee, CA 92071
Company Phone:	(619) 415-0103
Contact Person:	David Stroup Managing Partner dkstroup@pathwaynpi.com
Date:	August 20, 2018

Device Identification

Device Trade Name:	PSM 3-Way Silicone Foley Catheter
Common Name:	Foley Catheter
Classification Name(s):	Urological catheter and accessories
Classification Regulation(s):	876.5130
Device Class:	Class II
Product Code(s):	EZL
Advisory Panel:	Gastroenterology/Urology

Identification of Predicate Devices

Device Name	Regulation No.	Product Code	510(K) Number	Clearance Date
3 Way Silicone Foley Balloon Catheter (MFG: Cook)	876.5130 Urological catheter and accessories	EZL	K091767	October 9, 2009

Device Description

The subject device is a single-use, latex-free, 3-way Foley catheter that is constructed of medical grade silicone. It incorporates three (3) lumens, one for inflation/deflation of the balloon, another for drainage, and the remainder for irrigation of the urinary tract.

The balloon, at the distal end of the catheter, is inflated to fill volume between 10-30 ml and remains inflated via the incorporated two-way valve in the connector at the proximal end of the inflation lumen. The connector engages with slip/taper luer connection that is standard on syringes. With the balloon inflated, the catheter maintains position in the urinary tract for the

duration of the clinical application. Prior to removal, the balloon is deflated via the two-way valve connection.

The drainage inlet is located distal to the catheter's balloon. The connection to the urinary bag is a standard non-interconnectable connector.

The irrigation outlet is located just proximal of the catheter's balloon. It is positioned underneath a sleeve, which directs fluid in the proximal direction towards the 3-way connection. The purpose of the sleeve is to disperse the irrigation fluids gently down the urinary tract. The connector for the irrigation lumen is a standard non-interconnectable connector.

Indications for Use

Urological catheter intended for drainage/irrigation of the urinary tract. Catheterization is accomplished through the urinary tract, but also suprapubic placement or by nephrostomy. Intended population is adults and pediatrics.

Comparison of Technological Characteristics with Predicate Device

Comparison Feature	PSM 3-Way Silicone Foley Catheter	Predicate Device 3 Way Silicone Foley Balloon Catheter
Indications for Use	Urological catheter intended for drainage/irrigation of the urinary tract. Catheterization is accomplished through the urinary tract, but also suprapubic placement or by nephrostomy. Intended population is adults and pediatrics.	Used to provide continuous bladder irrigation of fluids and drainage of urine from the urinary tract. Urinary tract access is generally accomplished by insertion of the catheter through the urethra and into the bladder but may also be accomplished by suprapubic placement or by Nephrostomy.
Type	3-way with inflation, drainage, and irrigation lumens	3-way with inflation, drainage, and irrigation lumens
Size Offering	14, 16, 18 Fr	16, 18, 20, 22, 24, 26 Fr
Material	Silicone, Medical Grade	Silicone, Medical Grade
Working Length	36 cm	34 cm
Inflation Volume	10-30 ml	30 ml
Performance Standard	ASTM F623	ASTM F623
Indwelling Time	Up to 30 days	Up to 30 days
Single-Use?	Yes	Yes
Prescription Use?	Yes	Yes
Sterile?	Yes	Yes

Summary of Testing Performed

The test program was performed in accordance to FDA guidance and recognized performance states, which includes the following:

- Biocompatibility
- Sterilization
- Packaging Integrity (i.e., Sterile Barrier)
- Transportation
- Shelf-Life

- Performance/Functionality

Successful results were achieved with all evaluations conducted.

Conclusion

The PSM 3-Way Silicone Foley Catheter has demonstrated it is substantially equivalent to the commercially available predicate.