April 21, 2020

Pathway, LLC
Aaron Rogers
Director of Regulatory and Quality
8779 Cottonwood Avenue, Suite 105
Santee, CA 92071

Re: K192034
Trade/Device Name: HDX 100% Silicone 2-way Foley Catheter, 14Fr/10cc
HDX 100% Silicone 2-way Foley Catheter, 16Fr/5cc
HDX 100% Silicone 2-way Foley Catheter, 18Fr/10cc
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL
Dated: March 19, 2020
Received: March 23, 2020

Dear Aaron Rogers:

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,

Purva Pandya
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192034

Device Name
HYDROPHILIX 100% Silicone 2-Way Foley Catheter, 14Fr/10cc
HYDROPHILIX 100% Silicone 2-Way Foley Catheter, 16Fr/5cc
HYDROPHILIX 100% Silicone 2-Way Foley Catheter, 18Fr/10cc

Indications for Use *(Describe)*
Urological catheter is intended for drainage of the urinary tract. Catheterization is accomplished by inserting the catheter through the urethra and into the bladder. 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.

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510(K) SUMMARY – K192034

Submitter Information

Company Name:	Hydrophilix, Inc.
Company Address:	12100 Wilshire Blvd Suite 800 Los Angeles, CA 90025
Contact Person:	Aaron Rogers Pathway, LLC. Director of Regulatory & Quality (619) 415-0103 arogers@pathwaynpi.com
Date:	April 21, 2020

Device Identification

Device Trade Name:	HYDROPHILIX 100% Silicone 2-Way Foley Catheter, 14Fr/10cc HYDROPHILIX 100% Silicone 2-Way Foley Catheter, 16Fr/5cc HYDROPHILIX 100% Silicone 2-Way Foley Catheter, 18Fr/10cc
Common Name:	Foley Catheter
Classification Name:	Urological catheter and accessories
Classification Number:	876.5130
Regulatory Class:	Class II
Product Code(s):	EZL
Product Code Name:	Catheter, Retention Type, Balloon
Advisory Panel:	Gastroenterology/Urology

Identification of Predicate Device

Predicate Device				
Device Name	Regulation No.	Product Code	510(K) Number	Clearance Date
Bardex Lubi-Sil Foley Catheter	876.5130 - Urological catheter and accessories	EZL	K984084	February 1, 1999

Device Description

The Subject Device is a single-use, 2-way Foley catheter that is constructed of medical grade silicone. It incorporates two (2) lumens, one for inflation/deflation of the balloon and the other for drainage of the urinary tract.

The balloon, at the distal end of the catheter, is inflated to the labeled fill volume 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 2-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 Subject Device is packaged inside a perforated plastic sleeve that is inserted into a sterile barrier pouch. Ten (10) units are packaged into a carton, which is the saleable unit. The Subject Device is terminally sterilized via Ethylene Oxide (EO).

The Subject Device will be initially offered in 14, 16, 18Fr sizes. The entire length of the Subject Device is disposable. The Subject Device is not sold as a set, there are no accessories or components included.

Indications for Use

Urological catheter intended for drainage of the urinary tract. Catheterization is accomplished by inserting the catheter through the urethra and into the bladder. Intended population is adults and pediatrics.

Comparison of Technological Characteristics with Predicate Device

Comparison Table – Subject and Predicate Devices		
Comparison Feature	**Subject Device**	**Predicate Device**
Indications for Use	Urological catheter intended for drainage of the urinary tract. Catheterization is accomplished through the urinary tract. Intended population is adults and pediatrics.	Used in the drainage and/or collection and/or measurement of urine. Generally, drainage is accomplished by inserting the catheter through the urethra and into the bladder. However, drainage is sometimes accomplished by suprapubic or other placement of the catheter, such as a nephrostomy tract.
Type	2-way with inflation and drainage lumens	2-way with inflation and drainage lumens
Size/Balloon Size	14Fr/10cc 16Fr/5cc 18Fr/10cc	8, 10Fr/3cc Balloon 12-24Fr, even sizes/5cc Balloon 16-24Fr, even sizes/30cc Balloon
Material	Silicone, Medical Grade	Silicone, High Grade
Performance Standard	ASTM F623	ASTM F623
Single-Use?	Yes	Yes
Prescription Use?	Yes	Yes
Sterile?	Yes	Yes

Summary of Evaluations 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
- Performance/Functionality

Successful results were achieved with all evaluations conducted.

Conclusion

The Subject Device has demonstrated it is substantially equivalent to the commercially available predicate.