September 18, 2024

InnoCare Urologics, LLC
Patrick Mccain
VP, QA/RA
7175 SW 47th Street, Suite 207
Miami, Florida 33155

Re: K241424
Trade/Device Name: InnoCare Specialty Foley Catheter
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and accessories
Regulatory Class: II
Product Code: EZL, SCT
Dated: August 21, 2024
Received: August 21, 2024

Dear Patrick Mccain:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sharon M. Andrews -S

for Jessica N. 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)*
K241424

Device Name
InnoCare Specialty Foley Catheter

Indications for Use *(Describe)*
The InnoCare Specialty Foley Catheter is intended for urethral catheterization for urological bladder drainage. The device is indicated for adult use only with a maximum indwell time of no more than 30 days.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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TRADITIONAL 510(k) SUMMARY

1. SUBMITTER INFORMATION

Applicant Name:	InnoCare Urologics, LLC
Applicant Address:	7175 SW 47th Street, Suite 207
	Miami FL 33155, United States
Contact Telephone:	(855) 466-6305
Applicant Contact:	Patrick McCain, VP, QA/RA
Contact Email:	pmccain@innocareurologics.com
Date Prepared:	May 17, 2024

2. DEVICE NAME

Trade or Proprietary Name:	InnoCare Specialty Foley Catheter
Common or Usual Name:	Foley Catheter
Classification Regulation:	21 CFR 876.5130
Device Class:	II
Product Code:	EZL (Catheter, Retention Type, Balloon),
	SCT (Foley Catheters and Accessories with Additional Safety Features)
Panel:	Gastroenterology/Urology

3. PREDICATE DEVICE IDENTIFICATION

Predicate Device:	Medline Silicone Foley Catheter (K142635)

4. DEVICE DESCRIPTION

The InnoCare Specialty Foley Catheter is a 16 French, two-way silicone Foley catheter for urethral catheterization to drain urine from the bladder. The catheter is retained in the bladder by use of a retention balloon attached to the distal end of the catheter. The device is offered in a straight tip configuration and a Coude tip configuration.

The inflation lumen of the catheter contains a secondary balloon deflation mechanism. This mechanism is designed to provide a fluid escape pathway to allow for balloon deflation in the event of a forced withdrawal or catheter pullout.

The device is provided sterile and for single use.

5. INDICATIONS FOR USE

The InnoCare Specialty Foley Catheter is intended for urethral catheterization for urological bladder drainage. The device is indicated for adult use only with a maximum indwell time of no more than 30 days.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparison Element	**Subject Device:** InnoCare Specialty Foley Catheter	**Predicate Device:** Medline Silicone Foley Catheter (K142635)
Indications for Use	The InnoCare Specialty Foley Catheter is intended for urethral catheterization for urological bladder drainage. The device is indicated for adult use only with a maximum indwell time of no more than 30 days.	Medline silicone Foley catheters are intended to be placed in the bladder, through the urethra, to drain urine into a collection device. Two-way catheters are intended for urological bladder drainage only. Three-way catheters are intended for urological bladder drainage and bladder irrigation.
Product Code	EZL, SCT	EZL
Regulation	21 CFR 876.5130	21 CFR 876.5130
Prescription use (Rx)/ Over the counter (OTC)	Rx	Rx
Indwell Time	No more than 30 days	No more than 30 days
Lumen	Two-Way	Two-Way or Three- Way
Primary Shaft Material	Silicone	Silicone
Catheter Size	16 Fr	12 Fr – 24 Fr
Catheter Length	17”	17”
Inflation Volume	10 mL	10 mL – 30 mL
Balloon Deflation	Via syringe through Luer-activated valve.	Via syringe through Luer-activated valve.
Secondary Balloon Deflation Mechanism	The inflation lumen of the catheter contains a secondary balloon deflation mechanism. This mechanism is designed to provide a fluid escape pathway to allow for balloon deflation in the event of a forced withdrawal or catheter pullout.	No secondary balloon deflation mechanism.
Tip Shapes	Straight, Coude	Straight, Coude
Sterilization	Ethylene Oxide	Ethylene Oxide

As evidenced by the above table, both the subject and the predicate devices have the same intended use, but the subject and the predicate devices have different technological characteristics.

Performance testing was conducted on the subject device, and it was established that the differences in technological characteristics between the subject and the predicate do not raise different questions of safety or effectiveness.

7. SUMMARY OF NON-CLINICAL TESTING

Device performance data was provided in support of the substantial equivalence determination.

BIOCOMPATIBILITY TESTING:

Biocompatibility testing was conducted per ISO 10993-1:2018. The following tests were conducted:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Subacute Systemic Toxicity
- Genotoxicity
- Implantation

The results of this testing demonstrate that the subject device is biocompatible for its intended use.

BENCH TESTING:

Bench testing of the subject device included dimensional verification, functional and performance testing per ASTM F623:2019 requirements, simulated use testing of the secondary balloon deflation mechanism and Magnetic Resonance Compatibility testing per FDA Guidance (2023), *"Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment | FDA"*.

All pre-determined acceptance criteria were met. Performance testing demonstrates that the differences in technological characteristics between the subject and the predicate do not raise different questions of safety or effectiveness.

STERILITY, PACKAGING AND DISTRIBUTION:

The InnoCare Specialty Foley Catheter was validated to be sterilized using ethylene oxide per ISO 11135:2014. To support the claimed shelf life, performance testing and package integrity testing was conducted following environmental conditioning, simulated distribution and accelerated aging.

8. CONCLUSION

Based on the information presented in this submission, it can be concluded that the subject device is substantially equivalent to the predicate device.