January 13, 2023

Potrero Medical, Inc.
Priscila Tapia
Director of Regulatory and Quality Assurance
26142 Eden Landing Road
Hayward, CA 94545

Re: K221020
Trade/Device Name: Accuryn Monitoring System
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: EZL, EXY, PHU
Dated: December 12, 2022
Received: December 13, 2022

Dear Priscila Tapia:

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. 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)*
K221020

Device Name
Accuryn Monitoring System

Indications for Use *(Describe)*
The Accuryn Monitoring System is intended for use in the drainage and/or collection of urine, and in the monitoring of urine output and core body temperature, in degrees Fahrenheit and degrees Celsius. The Accuryn Monitoring System with the Accuryn Sensing Urinary Catheter (SmartFoley®) – IAP UO Temp is also intended for use in the monitoring of intra-abdominal pressure. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and the associated clinical syndrome of abdominal compartment syndrome (ACS). The Accuryn Sensing Urinary Catheter is a single use device intended for short term use (less 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

This 510(k) summary was prepared in accordance with 21 CFR 807.92
Prepared on January 13, 2023

510(k) Submitter / Holder: Potrero Medical, Inc.
26142 Eden Landing Road
Hayward, CA 94545
Establishment Registration No: 3011383638

Contact: Priscila Tapia
Director of Regulatory and Quality Assurance
Phone: 510-826-2033
Email: ptapia@potreromed.com

Subject Device

Device Trade Name:	Accuryn Monitoring System Accuryn SmartFoley IAP UO Temp Tray System 12 F Accuryn SmartFoley IAP UO Temp Tray System 14 F Accuryn SmartFoley IAP UO Temp Tray System 16 F
Device Common Name:	Temperature-sensing foley catheter, Intra-abdominal pressure monitoring device
Device Class:	II
Classification Regulation:	21 CFR §876.5130, Urological Catheter and Accessories
Regulation Description:	Urological Catheter and Accessories
Product Codes:	EZL, EXY, PHU
510(k) Type:	Traditional
Catalog Numbers:	FGN-06-2687, FGS-06-IAP.12FST, FGS-06-IAP.14FST

Predicate Device

The Accuryn Monitoring System with the Accuryn SmartFoley IAP UO Temp Tray System 12F and 14F is being compared to the following legally marketed predicate device:

510(k) Number:	K153655
Manufacturer:	Potrero Medical, Inc.
Trade Name:	Accuryn Monitoring System Accuryn SmartFoley UO Temp Tray System Accuryn SmartFoley IAP UO Temp Tray System
Device Common Name:	Temperature-sensing foley catheter, Intra-abdominal pressure monitoring device
Catalog Numbers:	FGN-06-2687, FGS-06-IAP.16FST, FGS-06-UOT.16FST

The predicate has not been subject to a design-related recall

---

Device Description

The Accuryn Monitoring System consists of three components, the Accuryn Sensing Urinary Catheter, Accuryn Urine Collection Set or Accuryn SmartFoley Adapter, and the Accuryn Monitor.

The Accuryn Sensing Urinary Catheter is a single use, sterile, MR conditional, disposable (12F, 14F, and 16 F), two-way silicone urinary bladder catheter with two opposing drainage eyes and four lumens. The first lumen is for urine drainage, the second lumen for the retention balloon, the third lumen embedded with a thermistor, and the fourth lumen to measure intra-abdominal pressure (IAP).

The Accuryn SmartFoley® comes in three configurations**:**

- IAP, U/O, Temp (intra-abdominal pressure, urine output, and core temperature)
- U/O, Temp (urine output and core temperature)
- Adapter (that is compatible with commercially available Foley catheters between 6-24Fr)

The Accuryn Urine Collection Set is provided permanently pre-connected to the Accuryn Sensing Urinary Catheter. The catheter's drainage lumen conveys urine to a urine measurement cassette, which connects to the Accuryn Monitor. The cassette feeds the urine into a urine collection bag. Potrero Medical also provides a configuration of the Accuryn Urine Collection Set that is not provided pre-connected to the catheter/foley. It is known as Accuryn SmartFoley Adapter and enables the user to connect a Foley catheter of their choice to the Accuryn Urine Collection Set. The Accuryn Urine Collection Set and Accuryn SmartFoley Adapter function in conjunction with the Accuryn Monitor to measure and display urine output is considered a 510(k) exempt device per 21 CFR 876.1800 (urine flow or volume measuring system, product code EXY).

The Accuryn Monitor is a portable electronic device which maintains urine flow from the foley through the Accuryn Urine Collection Set or Accuryn SmartFoley Adapter, measures the urine output volume in the measurement cassette, and displays the urine output. The Accuryn Monitor also measures and displays the temperature from the thermistor and intra-abdominal pressure (IAP) from the pressure lumen. The monitor contains software.

Intended and Indications for Use

The Accuryn Monitoring System is intended for use in the drainage and/or collection of urine, and in the monitoring of urine output and core body temperature, in degrees Fahrenheit and degrees Celsius. The Accuryn Monitoring System with the Accuryn Sensing Urinary Catheter (SmartFoley®) – IAP UO Temp is also intended for use in the monitoring of intra-abdominal pressure. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and the associated clinical syndrome of abdominal compartment syndrome (ACS). The Accuryn Sensing Urinary Catheter is a single use device intended for

short term use (less than 30 days).

Technological Characteristics

The Accuryn SmartFoley IAP UO Temp Tray System 12 F and 14 F introduce two smaller size catheters which are similar in design characteristics and performance to the predicate device. The Accuryn Monitoring System displays the trending IAP value in the trending IAP graph screen, which differs from the predicate which only displays the trending IAP graph. However, the fundamental scientific technology used in the Accuryn Monitoring System, including the SmartFoley devices, is not affected by the addition of these two foley's sizes or the trending IAP display, and the mechanism of action, general principle of operation, and intended use, remain unchanged from the predicate. Performance testing data has demonstrated that the Accuryn Monitoring System is safe and effective for its intended use.

Comparison of Technological Characteristics and Device Use with Predicate Device

Comparison Table – Subject and Predicate Devices			
Comparison Feature	**Subject Device**	**Predicate Device**	**Comments**
Product Class	II	II	Same
Product Code	EZL, PHU, EXY	EZL, PHU, EXY	Same

Indications for Use	The Accuryn Monitoring System is intended for use in the drainage and/or collection of urine, and in the monitoring of urine output and core body temperature, in degrees Fahrenheit and degrees Celsius. The Accuryn Monitoring System with the Accuryn Sensing Urinary Catheter (SmartFoley®) – IAP UO Temp is also intended for use in the monitoring of intra- abdominal pressure. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and the associated clinical syndrome of abdominal compartment syndrome (ACS). The Accuryn Sensing Urinary Catheter is a single use device intended for short	The Accuryn Monitoring System is intended for use in the drainage and/or collection of urine, and in the monitoring of urine output and core body temperature, in degrees Fahrenheit and degrees Celsius. The Accuryn Monitoring System is also intended for use in the monitoring of intra-abdominal pressure. The measured pressures can be used as an aid in the diagnosis of intra-abdominal hypertension (IAH) and the associated clinical syndrome of abdominal compartment syndrome (ACS). The Accuryn Sensing Urinary	Subject device specifies the Accuryn Sensing Urinary Catheter (SmartFoley®) – IAP UO Temp is the catheter with intra-abdominal pressure measurement ability. The Accuryn SmartFoley UO Temp is an alternative option for users who do not need the IAP functionality.

	term use (less than 30 days).	Catheter is a single use device intended for short term use (less than 30 days).	
Use environment	The device is intended for use in the hospital, including the operative or intensive care environments.	The device is intended for use in the hospital, including the operative or intensive care environments.	Same
Users	The device is intended to be used by surgeons, anesthesiologists, nurses, and other clinical care personnel.	The device is intended to be used by surgeons, anesthesiologists, nurses, and other clinical care personnel.	Same
IAP UO Temp Catheter Size	12Fr 14Fr 16Fr	16Fr	Two smaller French sizes are being introduced.
Lumens	4 (IAP, UO, Temp, Retention)	4 (IAP, UO, Temp, Retention)	Same
Performance Standard	ASTM F623	ASTM F623	Same
Use Duration	Foley: <30 days Monitor: Re-usable	Foley: <30 days Monitor: Re-usable	Same
Sterile	Disposable: Yes Monitor: No	Disposable: Yes Monitor: No	Same

Summary of Non-Clinical Performance Data

The following testing was conducted to validate and verify that the subject device met all acceptance criteria and was substantially equivalent to the predicate device:

Design Verification and Validation Testing

- Urinary Catheter Tests per ASTM F623-19 and ISO 20696
- Performance Testing, including compliance with ASTM D3078-02, ASTM F88/F88M-15, ASTM D4332-14, ASTM D4169-16, ASTM F1980-16
- MR Compatibility per FDA Guidance “Testing and Labeling Medical Devices for Safety in

the Magnetic Resonance (MR) Environment", ASTM F2052-15, ASTM F2119-07, ASTM F2182-19e2, ASTM F2213-17, and ASTM F2503-20

- IAP Functionality Testing
- Usability per ANSI AMMI IEC 62366-1
- System and Software Verification and Validation per IEC 62304

Electromagnetic Compatibility and Electrical Safety

- Testing and evaluation per IEC 60601-1, IEC 60601-1-2, IEC 80601-2-49, and ISO 80601-2-56

Cybersecurity

- Testing and risk assessment per FDA guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices" and AAMI TIR57

Sterilization

- Product adoption equivalency and evaluation per AAMI TIR28:2016, ISO 11607-1, ISO 11135, and FDA Guidance "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile"

Biocompatibility

- Biological Risk Assessment per ISO 10993, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process (2018) and the FDA Guidance "Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process" (2020), considering:
    - Cytotoxicity
    - Sensitization
    - Irritation: Intracutaneous Injection Test
    - Acute Systemic Toxicity
    - Material-Mediated Pyrogenicity
    - Subacute system toxicity
    - Genotoxicity
    - Implantation

Clinical Data

No clinical data was required to demonstrate safe use of the Accuryn Monitoring System with the Accuryn SmartFoley IAP UO Temp Tray System 12 F and 14 F.

Conclusion

Based on the similarities in design between the subject and predicate devices currently in use, and the performance data, the addition of the Accuryn SmartFoley IAP UO Temp Tray System 12 F and 14 F to the Accuryn Monitoring System for the proposed indication does not raise new questions related to safety and effectiveness compared with the predicate.

The Indications for Use statement for the subject device is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device, nor do they affect the safety and effectiveness of the device relative to the predicate.

Both the subject and the predicate devices have the same intended use for the drainage and/or collection of urine, and in the monitoring of urine output and core body temperature, in degrees Fahrenheit and degrees Celsius. Both the subject and predicate devices are also intended for use in the monitoring of intra-abdominal pressure. The Accuryn SmartFoley UO Temp is an alternative option for users who do not need the IAP functionality.

The fundamental scientific technology used in the Accuryn Monitoring System, including the SmartFoley devices, is not affected and the mechanism of action and general principle of operation, remain unchanged from the predicate. Performance testing and analysis of results provide assurance that the device meets its specifications, is acceptable for device functionality, and is safe and effective for its intended use without raising any new issues of safety and effectiveness as compared to the predicate. Therefore, the Accuryn Monitoring System with the Accuryn SmartFoley IAP UO Temp Tray System 12 F and 14 F is substantially equivalent to the Accuryn Monitoring System with the Accuryn SmartFoley IAP UO Temp Tray System 16 F.