DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 15, 2016

Potrero Medical, Inc.
Devyani Nanduri
Director of Clinical and Regulatory Affairs
101 Mississippi St.
San Francisco, CA 94107

Re: K153655
Trade/Device Name: Accuryn Monitoring System
Regulation Number: 21 CFR 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: Class II
Product Code: EZL, EXY, PHU
Dated: March 11, 2016
Received: March 14, 2016

Dear Devyani Nanduri,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153655

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 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.

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510(k) Summary

Accuryn Monitoring System

I. Submitter Information

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92
Submission Sponsor	Potrero Medical, Inc. 101 Mississippi St. San Francisco, CA 94107
Contact Person	Contact Person: Devyani Nanduri, PhD Phone: (415) 926-8618 Fax: (415) 800-7086
Date Prepared	December 18, 2015

II. Device

Name of Device	Accuryn™ Monitoring System Accuryn™ Sensing Urinary Catheter, Accuryn™ Monitor
Common or Usual Name	Temperature-sensing Foley catheter, Intra-abdominal pressure monitoring device
Classification Name	Catheter, Retention Type, Balloon (21 CFR 876.5130) Intra-Abdominal Pressure Monitoring Device (Unclassified)
Regulatory Class	II
Product Code(s)	EZL, PHU, EXY

III. Predicate Devices Bardex Latex-Free Temperature Sensing Foley Catheter (K070582)
Bard Intra-abdominal Pressure Monitoring Device (K070201)

IV. Device Description

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

The Accuryn Sensing Urinary Catheter is a single use, sterile, MR conditional, disposable 16 French, two-way silicone urinary bladder catheter with two opposing drainage eyes and 4 lumens.

The first lumen of the Urinary Catheter is for urine drainage and is packaged pre-connected to the Accuryn Urine Collection Set. The Accuryn Urine Collection Set functions in conjunction with the Accuryn Monitor to measure and display urine output and is considered a 510(k) exempt device per 21 CFR 876.1800 (urine flow or volume measuring system, product code EXY).

The second lumen is for the 5cc retention balloon, which serves to keep the catheter in place. Inflation of the retention balloon is provided by connecting a barrel tip syringe filled with sterile water to the catheter by means of a two-way valve. Sterile water is conveyed through the retention balloon lumen to inflate the retention balloon; water is contained within the balloon to maintain retention; the water is removed by reopening the valve to deflate the balloon prior to removing the catheter from the bladder.

The third lumen contains a thermistor wire for monitoring a patient's core body temperature in degrees Fahrenheit and degrees Celsius when connected to the Accuryn Monitor.

The fourth lumen consists of a closed air column that connects to a pressure transducer inside the Accuryn Monitor. Intra-abdominal pressure is measured via this lumen and displayed on the Monitor screen.

V. 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 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).

VI. Substantial Equivalence

The Accuryn Monitoring System utilizes substantially equivalent performance attributes as the predicate devices. Similarities to the predicate device include the following:

- Provided Sterile
- Single Use
- Materials used
- Performance standard ASTM F623-99(2006)
- Urinary catheter properties (shaft color, shaft diameter, retention balloon size)
- Temperature measurement functionality
- Pressure measurement functionality

Differences in technological characteristics between the Accuryn Monitoring System and the predicate devices do not raise different questions of safety and effectiveness. Accepted scientific methods exist for assessing the effect of these different characteristics, such as bench and biocompatibility testing.

VII. Performance Data

Biocompatibility testing was conducted in accordance with ISO 10993-1:2009/(R)2013*, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process* and FDA Draft Guidance, Use of International Standard ISO 10993 "Biological Evaluation of Medical Devices Part 1: Evaluation of Testing." Performance bench testing was performed per ASTM F623-99 (2006), *Standard Performance Specification for Foley Catheter and Coefficient of Friction testing*. MR compatibility testing was conducted in accordance with ASTM F2052-14, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*, ASTM F2213-06 (R2011), *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment,* ASTM F2182-11a, *Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging*, and ASTM F2119-07 (R2013), *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants.* Software-related documentation provided was provided in accordance with FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (2005) for Moderate Level of Concern device. The Accuryn Monitoring System meets the requirements of basic safety and essential performance as defined by the IEC 60601-1 2005 3rd Edition, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* and complies with IEC 60601-1-2 2007, *Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*.

VIII. Conclusions

Results from the bench tests for design verification and validation have proven acceptable performance on all tests to indicate that the device is suitable for its intended use and is as safe and effective as the predicate devices to support a determination of substantial equivalence.