June 1, 2020

ProCell Surgical, Inc.
% Sharyn Orton
Senior Consultant
MEDIcept Inc.
200 Homer Ave
Ashland, Massachusetts 01721

Re: K193361
Trade/Device Name: ProCell Surgical Sponge-Blood Recovery Unit
Regulation Number: 21 CFR 868.5830
Regulation Name: Autotransfusion Apparatus
Regulatory Class: Class II
Product Code: CAC
Dated: April 28, 2020
Received: April 30, 2020

Dear Sharyn Orton:

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,

for Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K193361

Device Name
ProCell™ Surgical Sponge - Blood Recovery Unit

Indications for Use *(Describe)*
ProCell™ facilitates the extraction of blood from surgical sponges as a preliminary step in the process of intraoperative autotransfusion or IAT.

ProCell™ functions as a blood collection device only and does not filter or otherwise process the blood recovered. As an accessory to IAT, it is used in conjunction with standard IAT equipment which processes the blood retrieved from ProCell™ prior to reinfusion into the patient (autologous blood transfusion).

Designed for ease-of-use directly on the surgical instrument table, the disposable ProCell™ can be used repeatedly during a surgical case and provides an alternative to other sponge-blood recovery methods including hand-wringing.

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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Traditional 510(k) Summary
as required by 21CFR 807.92(a)

A) Submitted by:

ProCell Surgical, Inc.
19 Menin Road
Toronto, Ontario M6C3J1
Canada

Contact: Sharyn Orton, Ph.D.
MEDIcept, Inc.
200 Homer Ave.
Ashland, MA 01721
401-330-8264

Date Prepared: December 2, 2019

B) Classification Name: Apparatus, Autotransfusion
Proprietary Name: ProCell™ Surgical Sponge – Blood Recovery Unit
Common/Usual Name: ProCell™ Surgical Sponge – Blood Recovery Unit
Device Regulation: 21 CFR 868.5830
Class: II
Product Code: CAC
Review Panel: Anesthesiology

C) Predicate: K140205 Teleflex Medical, Inc. Pleur-Evac Sahara Plus Continuous Reinfusion and Autotransfusion System

D) Device Description:

The ProCell™ Surgical Sponge - Blood Recovery Unit ("ProCell") automates the manual hand-wringing process to extract blood from surgical sponges. The ProCell unit consists of three components 1) a piston Lid, 2) a perforated Sponge Basket, and 3) a Reservoir. The Sponge Basket is inserted into the Reservoir, and the piston Lid is placed on the top opening of the Reservoir. Through the use of standard Operating Room vacuum suction, blood is extracted from the sponges and is collected in the Reservoir.

ProCell is used in conjunction with standard intraoperative autotransfusion devices (IAT) which must process the blood retrieved from ProCell prior to reinfusion into the patient. ProCell functions as a blood collection device only, is not a blood storage container, and does not filter or otherwise process the recovered blood. The recovered blood from ProCell is not intended to be infused directly back into the patient.

E) Intended Use/Indications for Use

ProCell™ facilitates the extraction of blood from surgical sponges as a preliminary step in the process of intraoperative autotransfusion or IAT.

ProCell™ functions as a blood collection device only and does not filter or otherwise process the blood recovered. As an accessory to IAT, it is used in conjunction with standard IAT equipment which processes the blood retrieved from ProCell™ prior to reinfusion into the patient (autologous blood transfusion).

Designed for ease-of-use directly on the surgical instrument table, the disposable ProCell™ can be used repeatedly during a surgical case and provides an alternative to other sponge-blood recovery methods including hand wringing.

F) Technological Characteristics and Substantial Equivalence Comparison to Predicate Device

The ProCell device is substantially equivalent to the Pleur-Evac Sahara Plus Continuous Reinfusion and Autotransfusion System (Pleur-Evac) predicate device in that both devices are an accessory to an Autotransfusion Apparatus regulated under 21 CFR 868.5830, Product Code CAC and intended for blood collection only. Both devices are single case-use sterile devices that operate through a vacuum assist and do not process the collected blood. Both devices must have the collected blood sent to the autotransfusion equipment for processing prior to patient reinfusion.

The ProCell device is different from the Pleur-Evac predicate device in that the Pleur-Evac is an accessory to a closed chest drainage system which is attached though patient tubing from the device to the patient's chest tube during immediate post-operative period for blood collection to prevent complications related to fluid accumulation, while the ProCell device is a self-contained unit which extracts and collects blood from surgical sponges. The Pleur-Evac is initially setup at the operating room table but once connected to the patient, is passed off the table and handled in a non-sterile fashion. The internal parts and contents remain sterile when the closed system is maintained. ProCell remains on the operating room instrument table (sterile field) for the duration of the procedure and can be used multiple times throughout the case.

G) Performance Testing and Standards Compliance

The following testing has been conducted:

- Biocompatibility
- Sterilization
- Packaging and shelf life
- Functional and structural integrity
- Operational performance
- Red blood cell viability

Testing has been conducted in compliance with the following standards:

- ISO 10993-1 Fifth Edition 2018-08, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
  - Consistent with ANSI/AAMI/ISO 10993-1:2009 (R)2013
- ISO 10993-4: 2017, Biological evaluation of medical devices--Part 4: Selection of tests for interactions with blood
- AAMI/ANSI/ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11: 2017, Biological Evaluation of Medical Devices - Part 11: Tests For Systemic Toxicity
- ISO 10993-12: 2012, Biological Evaluation of Medical Devices. – Part 12: Sample preparation and reference materials. As appropriate, standard surface area extraction ratios (for the devices) were used.
- 41 USP NF36:2018 <85> Bacterial Endotoxins Test (USP Rabbit Test)
- ASTM F2382-18, Standard Test Method for Assessment of Intravascular Medical Device Materials on Partial Thromboplastin Time (PTT)
- ASTM F2888-19 Standard Practice For Platelet Leukocyte Count - An In-Vitro Measure For Hemocompatibility Assessment Of Cardiovascular Materials
- ASTM F756-17, Standard Practice for Assessment of Hemolytic Properties of Materials
- ISO 15223-1:2016, Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
- ISO 11137-1:2006/A1:2013, Sterilization of health care products -- radiation -- part 1: requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 11137-2:2013, Sterilization of health care products - radiation - part 2: establishing the sterilization dose
- ISO 11737-1: 2018, Sterilization Of Health Care Products - Microbiological Methods - Part 1: Determination Of A Population Of Microorganisms On Products
- BS EN ISO 11737-2: 2009, Sterilization Of Medical Devices - Microbiological Methods - Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process
  - Consistent with ISO 11737-2:2009
- 41 USP NF36:2018 <151> Pyrogen Test
- ASTM D4169-16, Standard practice for performance testing of shipping containers and systems
- ASTM F88/F88M-15, Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F2096-11, Standard test method for detecting gross leaks in packaging by internal pressurization (bubble test)
- ANSI/AAMI/ISO 11607-1: 2019, Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems
  - Consistent with ISO 11607-1:2019

- ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
- ASTM D5276-98(2017), Standard Test Method for Drop Test of Loaded Containers by Free Fall
- ASTM D642-15, Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads
- ASTM D999-08, Standard Test Methods for Vibration Testing of Shipping Containers
- ASTM F4728-17, Standard Test Method for Random Vibration Testing of Shipping Containers

H) Conclusion

The ProCell Surgical Sponge-Blood Recovery Unit is substantially equivalent to the Pleur-Evac Sahara Plus Continuous Reinfusion and Autotransfusion System. The ProCell Surgical Sponge-Blood Recovery Unit has demonstrated that it will perform per its intended use.