



February 23, 2026

Smart Reactors  
% Robin Stephens  
CEO  
Psephos Biomedica  
Sussex Innovation Centre  
Science Park Square  
Falmer, BN1 9SB  
United Kingdom

Re: K260043

Trade/Device Name: Smart Reactors Camouflage Coated Extracorporeal Cardiopulmonary Tubing Set (SR180C)

Regulation Number: 21 CFR 870.4210

Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing

Regulatory Class: Class II

Product Code: DWF

Dated: January 6, 2026

Received: January 7, 2026

Dear Robin Stephens:

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
Kathleen M.  
Grunder -S

for Nicole Gillette

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

## Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K260043

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Please provide the device trade name(s).

?

Smart Reactors Camouflage Coated Extracorporeal Cardiopulmonary Tubing Set (SR180C)

Please provide your Indications for Use below.

?

The Smart Reactors Camouflage Coated Extracorporeal Cardiopulmonary Circuit Tubing Set is indicated for use in the extracorporeal circuit during cardiopulmonary bypass (CPB) surgical procedures for  $\leq 6$  hours.

Please select the types of uses (select one or both, as applicable).

Prescription Use ([21 CFR 801 Subpart D](#))

Over-The-Counter Use ([21 CFR 801 Subpart C](#))

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**510(k) Summary: K260043**

**Smart Reactors Camouflage Coated  
Extracorporeal Cardiopulmonary Tubing**

**Submission Sponsor:** Smart Reactors  
1st Floor, Block 15, Galway Technology Park  
Parkmore Road, Galway, H91 AY0Y, Ireland

Company Phone No.: +353-872-037-556

Applicant Contact: Mark Brassil  
Email: [mark@smartreactors.com](mailto:mark@smartreactors.com)

Correspondent Contact: Mr Robin Stephens  
Email: [rstephens@psephos.com](mailto:rstephens@psephos.com)

**Date Prepared:** February 23, 2026

***Device Identification***

**Trade/Proprietary Name:** Smart Reactors Camouflage Coated Extracorporeal  
Cardiopulmonary Tubing SR180C

**Common/Usual Name:** Tubing Sets

**Classification Name:** Cardiopulmonary bypass vascular catheter, cannula, or tubing

**Regulation Number:** 21 CFR 870.4210

**Product Code:** DWF

**Device Class:** II

**Predicate Device(s):** Tubing Pack (K171979)

**Indication for Use Statement**

The Indications for Use are the same as the predicate and are as follows:

The Smart Reactors Camouflage Coated Extracorporeal Cardiopulmonary  
Circuit Tubing is indicated for use in the extracorporeal circuit during  
cardiopulmonary bypass (CPB) surgical procedures for  $\leq 6$  hours.

This device is intended for use in the adult patient population.

**Device Description**

The Smart Reactors Camouflage Coated Extracorporeal Cardiopulmonary Tubing is a tubing pack intended for use during cardiopulmonary bypass. The tubing is DOP free polyvinylchloride (PVC) with an inner diameter of 9.5mm coated with Smart Reactors' proprietary Camouflage coating provided in a length of 180cm.

## Technological Characteristics and Product Feature Comparison

The subject device, the Smart Reactors Camouflage Coated Extracorporeal Cardiopulmonary Tubing, is substantially equivalent to the primary predicate device in terms of:

- indications for use
- materials
- technological characteristics
- performance criteria
- packaging and sterilization of devices

It does not raise any new questions compared to the predicate devices as outlined in the comparison table below.

Device	Smart Reactors Camouflage Coated Extracorporeal Cardiopulmonary Tubing	Medtronic, Inc. Tubing Pack K171979
<b>Product Name</b>	Smart Reactors Camouflage Coated Extracorporeal Cardiopulmonary Tubing	Medtronic, Inc. Tubing Pack
<b>Regulation No.</b>	870.4210	870.4210
<b>Regulation Name</b>	Cardiopulmonary bypass vascular catheter, cannula, or tubing	Cardiopulmonary bypass vascular catheter, cannula, or tubing
<b>Product Code</b>	DWF	DWF
<b>Classification</b>	Class II	Class II
<b>Indications for Use</b>	The Smart Reactors Camouflage Coated Extracorporeal Cardiopulmonary Circuit Tubing is a tubing pack indicated for use in the extracorporeal circuit during cardiopulmonary bypass (CPB) surgical procedures.	The Medtronic, Inc. Tubing Pack is indicated for use in the extracorporeal circuit during cardiopulmonary bypass (CPB) surgical procedures.
<b>Target Population</b>	Adult patients requiring cardiopulmonary bypass procedures for periods up to 6 hours	Patients requiring cardiopulmonary bypass procedures for periods up to 6 hours
<b>Target User</b>	Perfusionist	Perfusionist
<b>Biocompatibility Requirements</b>	In compliance with ISO 10993 series	In compliance with ISO 10993 series
<b>Main Contacting Materials</b>	DOP-free Polyvinyl Chloride (PVC) coated with Camouflage coating.	DOP-free polyvinyl chloride (PVC) Polycarbonate (PC) Cortiva, Trillium and Balance coating
<b>Single Use</b>	Yes	Yes
<b>Sterile Condition</b>	Sterile	Sterile
<b>Description of Sterilization method</b>	EtO sterilization process	EtO sterilization process
<b>Shelf Life</b>	2 years	2 Years

## **Testing Summary**

The device passed all performance bench testing in accordance with internal requirements, national standards and international standards. Specific standards utilized and tests performed included:

- ISO 15676:2016 "Cardiovascular implants and artificial organs – Requirements for single use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)".
- ISO 18193:2021 " Cardiovascular implants and artificial organs - Cannulae for extracorporeal circulation "
- EN 13868:2002 "Catheters - Test methods for kinking of single lumen catheters and medical tubing"
- ISO 11658:2012 "Cardiovascular implants and extracorporeal systems –Blood/tissue contact surface modifications for extracorporeal perfusion systems"

## **Biocompatibility**

A biological risk assessment has been completed for the subject device. To support this, biocompatibility testing was successfully completed in accordance with the ISO 10993 series of standards. The device was found to be biocompatible.

## **Statement of Substantial Equivalence**

Smart Reactors Camouflage Coated Extracorporeal Cardiopulmonary Tubing has the same intended use and indications for use, and equivalent technological characteristics compared to the predicate device. Therefore, the device is substantially equivalent to the predicate device.