



July 10, 2025

LivaNova USA inc
% Martina Carlini
RA Specialist
Sorin Group Italia S.r.l.
86, Via statale 12 Nord
Mirandola, 41037
Italy

Re: K250283

Trade/Device Name: RAP Femoral Arterial Cannulae
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Vascular Catheter, Cannula, Or Tubing
Regulatory Class: Class II
Product Code: DWF
Dated: June 11, 2025
Received: June 11, 2025

Dear Martina Carlini:

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,

Nicole M. Gillette -S

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

Submission Number (if known)

K250283

Device Name

RAP Femoral Arterial cannulae (200-100; 200-150)

Indications for Use (Describe)

The Remote Access Perfusion (RAP) femoral venous cannula is intended for use as a venous drainage cannula during cardiopulmonary bypass up to six hours

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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510(k) Summary
(in accordance with 21 CFR 807.92)

510(k) Number: K250283

I. Applicant Information

Applicant:

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Date Prepared:

July 10th 2025

II. Subject Device Identification

Device Trade Name:	RAP Femoral Arterial cannulae
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Classification:	Class II
Classification Panel:	Cardiovascular

III. Predicate Device

The RAP Femoral Arterial cannulae are substantially equivalent to the following cleared predicate device. Both modified and unmodified models have the same fundamental scientific technology and intended use:

510(k) Number:	K052081
Device Trade Name:	Remote Access Perfusion (RAP) Femoral Venous cannula
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing
Regulation Number:	21 CFR 870.4210
Product Code:	DWF
Classification:	Class II
Classification Panel:	Cardiovascular

IV. Device Description

RAP Femoral venous cannulae are single-use, non-toxic, non-pyrogenic fluid path devices and supplied sterile and individually packaged.

The device is composed of a cannula and a malleable obturator inserted into the cannula to allow the placement of the cannula along the femoral vein till the vena cava. The cannula and the obturator are packaged within the same pouch and sold together.

The cannula is an open lumen PVC polymer tube incorporating wire reinforcement in distal sections. The distal sections of the cannula are perforated with multiple holes at multiple stages to allow fluid flow. The clear proximal section is not reinforced to allow clamping; the proximal end terminates in a 3/8" to 1/2" barbed connector for standard cardiopulmonary bypass tubing.

The RAP femoral arterial cannulae are the modified version of the disposables currently marketed as the RAP Femoral Venous cannula (K052081).

Both modified and unmodified cannulae models are recommended for use as a venous drainage cannula during cardiopulmonary bypass up to six hours

V. Indications for Use

The Remote Access Perfusion (RAP) femoral venous cannula is intended for use as a venous drainage cannula during cardiopulmonary bypass up to six hours

VI. Summary of Technical Characteristics

The RAP Femoral arterial cannulae have the same fundamental technological characteristics, principles of operation and control mechanisms as the unmodified devices.

The PVC material of the basket, body and tip of the RAP Femoral venous cannulae were changed within the modified RAP femoral venous cannula in order to remove the diethylhexyl phthalate (DEHP) used as plasticizer currently present in the device. No other design changes have been made to the devices.

The devices are ethylene oxide sterilized and have a non-pyrogenic fluid path. They are for single use only.

VII. Non-Clinical Performance Data

Livanova USA Inc. has conducted extensive verification and validation testing of the RAP femoral venous cannula.

The devices passed all the testing in accordance with national and international standards.

In particular, the performed tests are the following:

TEST CLASSIFICATION	TEST DESCRIPTION
Verification/Validation	Visual inspection
Verification/Validation	Connector testing 180° pull test
Verification/Validation	Cannula clamp test
Verification/Validation	Blood pathway integrity
Verification/Validation	Flow rate and pressure drop through cannulae
Verification/Validation	Cannula kink test
Verification/Validation	Label legibility
Verification/Validation	Drainage cannula collapse resistance
Verification/Validation	Cannula integrity
Verification/Validation	Pull strength
Verification/Validation	Blood trauma characterization test
Biocompatibility	Cytotoxicity
Biocompatibility	Intracutaneous reactivity
Biocompatibility	Sensitization
Biocompatibility	Systemic Toxicity
Biocompatibility	Pyrogenicity (material mediated)
Biocompatibility	Hemocompatibility (Hemolysis, Coagulation, Complement activation, Platelet and Leukocyte count assay)
Biocompatibility	Genotoxicity (Mutation Assay, Mouse lymphoma)

VIII. Clinical Performance Data

No clinical testing was conducted in support of the RAP Femoral venous cannulae, as the indications for use and technical characteristics are equivalent to those of the predicate devices, which have been on the market for several years with proven safety and efficacy of use. The non-clinical testing summarized in this submission supports the substantial equivalence of the subject devices with the predicate devices when used according to their intended use.

IX. Statement of Substantial Equivalence

Based on equivalent intended use and technological characteristics, as well as on equivalent performance testing, the RAP femoral venous cannulae can be deemed to be substantially equivalent to their predicate devices:

- the unmodified RAP femoral venous cannulae, cleared under K052081;

The RAP femoral venous cannulae, as designed and manufactured, do not raise new questions regarding safety and effectiveness as compared to their predicate devices and are determined to be substantially equivalent to their predicate devices listed above.