



August 8, 2024

Livanova USA Inc
Tatjana Kuntschik
Principal Regulatory Affairs Specialist
14401 West 65th Way
Arvada, Colorado 80004

Re: K233702

Trade/Device Name: SMARxT Tubing and Connectors
Regulation Number: 21 CFR 870.4390
Regulation Name: Cardiopulmonary bypass pump tubing
Regulatory Class: Class II
Product Code: DWE
Dated: November 17, 2023
Received: July 10, 2024

Dear Tatjana Kuntschik:

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.

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

510(k) Number (if known)
K233702

Device Name
SMARxT Tubing and Connectors

Indications for Use (Describe)

The SMARxT Tubing and Connectors, a part of the Heart/Lung Perfusion Pack, are intended to be used in surgical procedures requiring extracorporeal support for periods of 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.

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
PRASStaff@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."

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	LIVANOVA USA INC
Applicant Address	14401 WEST 65th WAY Arvada CO 80004 United States
Applicant Contact Telephone	+49 89 32301-31
Applicant Contact	Tatjana Kuntschik
Applicant Contact Email	tatjana.kuntschik@livanova.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SMARxT Tubing and Connectors
Common Name	Cardiopulmonary bypass pump tubing
Classification Name	Tubing, Pump, Cardiopulmonary Bypass
Regulation Number	870.4390
Product Code	DWE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K981613	SMARxT Tubing and Connectors	DWE

Device Description Summary

21 CFR 807.92(a)(4)

The SMARxT Tubing and Connectors, subjects of this application are part of the Heart/Lung Perfusion Pack (K881330), a customized system of tubing and other devices built to user specifications designed for use during surgery requiring cardiopulmonary bypass.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SMARxT Tubing and Connectors, a part of the Heart/Lung Perfusion Pack, are intended to be used in surgical procedures requiring extracorporeal support for periods of up to six hours.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The SMARxT Tubings and Connectors (modified device) are substantially equivalent to its cleared predicate device. SMARxT Tubing and Connectors (modified device) and its cleared predicate device have the same indication for use. Minor wording updates do not change the intent and scope of the indication for use.

Technological Comparison

21 CFR 807.92(a)(6)

The SMARxT Tubing and Connectors subject device has the same principles of operation and design as the SMARxT Tubing and Connectors unmodified device.

The SMARxT Tubing and Connectors modified device and the SMARxT Tubing and Connectors unmodified device share the same fundamental technological characteristics except for the material of the surface treatment that does not affect the basic device function. Tegomer additive material is changing from Tegomer H-Si6440 P to H-Si6441 P blended into a polymeric resin for connectors and in polyvinylchloride (PVC) tubing which are components used in cardiopulmonary surgery perfusion circuits.

The two Tegomer products behave similarly when blended with PVC tubing.

Chemical analysis indicates that the two materials are chemically equivalent, and this is confirmed also by the performance testing and toxicological assessment.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The subject device was tested to ensure that it can provide all the capabilities necessary to operate safely and effectively. Applicable tests were carried out in accordance with the requirements of ISO 10993-1 standard as well as in compliance with the FDA guidance document Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" of September 4, 2020.

In vitro testing was performed to evaluate the impact of the different material in the modified SMARxT Tubing and Connectors version, specifically the following tests were carried out:

- Blood pathway integrity and coverage
- Surface Modification Integrity
- Hemolysis
- Connection testing
- Life to failure testing
- Spallation
- Cytotoxicity
- Direct and indirect Hemolysis

The modified device successfully met all acceptance criteria.

No clinical testing was conducted in support of the SMARxT Tubing and Connectors.

The results of in vitro studies demonstrate that the subject SMARxT Tubing and Connectors performs in a manner substantially equivalent to the unmodified SMARxT Tubing and Connectors predicate device with respect to the relevant functional parameters. The non-clinical testing summarized in this submission supports the substantial equivalence of these devices with their respective predicates.