April 1, 2021

LivaNova Deutschland GmbH
Mattia Ronchetti
Regulatory Affairs Director
Lindberghstr. 25
Munich, Bavaria 80939
Germany

Re: K202154
Trade/Device Name: B-Capta
Regulation Number: 21 CFR 870.4330
Regulation Name: Cardiopulmonary Bypass On-Line Blood Gas Monitor
Regulatory Class: Class II
Product Code: DRY
Dated: February 26, 2021
Received: March 1, 2021

Dear Mattia Ronchetti:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202154

Device Name
B-Capta

Indications for Use *(Describe)*

B-Capta is indicated for supplementary, in-line monitoring of the extracorporeal arterial oxygen partial pressure, venous oxygen saturation, venous hematocrit/hemoglobin, and arterial and venous temperature during cardiopulmonary bypass procedures 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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"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."

510(k) SUMMARY

I. SUBMITTER

Name:	LivaNova Deutschland GmbH
Address:	Lindberghstrasse 25 D-80939 München, Germany
Establishment Registration Number	9611109 (Manufacturer: LivaNova Deutschland: B-Capta Equipment) 9680841 (Manufacturing site : Sorin Group Italia- B-Capta Disposable)
Contact Person:	Florian Goetz
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Email:	florian.goetz@livanova.com
Secondary Contact:	Mattia Ronchetti
Phone:	+39 342 762 1974
Email:	mattia.ronchetti@livanova.com
Date Prepared:	July 31, 2020

II. DEVICE

Proprietary Name:	B-Capta
Common Name:	Extracorporeal blood-gas monitor
Classification Name:	Cardiopulmonary bypass on-line blood gas monitor
Regulation Number:	21CFR870.4330
Product Code:	DRY
Device Class:	Class II

III. PREDICATE DEVICE INFORMATION

B-Capta is substantially equivalent in function and intended use to ***SORIN DATA MASTER*** (K001388) and the ***SORIN B-CARE 5*** (K103168).

IV. INDICATIONS FOR USE

B-Capta is indicated for supplementary, in-line monitoring of the extracorporeal arterial oxygen partial pressure, venous oxygen saturation, venous hematocrit/hemoglobin, and arterial and venous temperature during cardiopulmonary bypass procedures up to six hours.

V. DEVICE DESCRIPTION

B-Capta is intended to be used for in-line continuous monitoring of patient's blood parameters during procedures requiring extracorporeal circulation.
B-Capta is designed to work with a Stöckert S5 System (K071318) heart-lung machine.

Provided in-line measured parameters of B-Capta are:
In the Venous line:

- Haematocrit / Haemoglobin (Hct/Hb)
- Venous blood oxygen saturation (sO_2)
- Venous blood temperature (venT)

In the Arterial line:

- Arterial blood oxygen partial pressure (pO_2)
- Arterial blood temperature (artT)

The duration of application is limited to 6 hours of continuous use.

B-Capta consist of the following components / disposables:

- B-Capta Venous and Arterial Sensors
- B-Capta Sensor Module
- B-Capta Venous and Arterial Reference Element Holders
- B-Capta disposable Venous and Arterial Cuvettes

B-Capta is a microprocessor based device. The venous sensor is an optical sensor which measures, when connected to its dedicated disposable cuvette, hematocrit/hemoglobin and oxygen saturation using an optical reflectance technology. Moreover, an infrared technology is used to measure the temperature of the venous blood.

The arterial sensor is an optical sensor which measures, when connected to its dedicated disposable cuvette, partial pressure of oxygen using an optical fluorescence technology. Moreover, an infrared technology is used to measure the temperature of the arterial blood.

Both sensors are functionally connected to the compatible heart-lung machine via a cable plugged in the sensor module and communicate with B-Capta firmware via a RS232 interface according to a dedicated communication protocol. Data are displayed on the graphical user interface of the heart-lung machine.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

LivaNova's B-Capta and its predicates have the same intended use, clinical setting, target user, target patient population, and principle of operation.
B-Capta provides arterial and venous blood measurements. Data Master also provides arterial and venous blood measurements, while B-Care5 provides only venous blood measurements. B-Capta is designed to work integrated with a Stöckert S5 System, as is B-Care5. Any differences between B-Capta and its predicates are minor and do not raise new issues of safety or effectiveness.

B-Capta and its predicate, Data Master have the following system functions:

- Blood parameters are measured or calculated in real time and displayed to users on a digital display
  - Haematocrit / Haemoglobin (Hct/Hb)
  - Venous blood oxygen saturation (sO_2)
  - Venous blood temperature (venT)
  - Arterial blood oxygen partial pressure (pO_2)
  - Arterial blood temperature (artT)
- Display may be adjusted by the user
- Display may provide alerts for user-defined alert limits

B-Capta and its predicate, B-care5 have the following system function:

- Integration into a heart lung machine

VII. PERFORMANCE DATA

The following non-clinical testing was performed to support the substantial equivalence of the B-Capta to its legally marketed predicate devices:

- Electromagnetic Compatibility and Electrical Safety
  - Evaluation for electrical safety and EMC testing was performed for B-Capta. B-Capta complies with IEC 60601-1 standard for electrical safety and IEC 60601-1-2 standard for EMC.
- Design Verification and Validation Testing
  - Design functionality testing confirms that the product meets its product requirements. Summative use testing following ISO 62366 confirms that the product fulfills user needs.
- Software verification and validation
  - Software verification and validation testing was completed successfully. The software level of concern is “moderate”.
- Sterilization and Shelf Life
  - The product (cuvettes only) is provided sterile with a 3-year shelf life. Product sterility, shelf life, and packaging/transport testing confirms product safety and effectiveness.
- Biocompatibility Testing
  - The sterile, disposable cuvettes in the system are limited blood-contacting, and have been tested per ISO 10993. Biocompatibility testing confirms that the products can be used as intended.

Animal testing was not required to demonstrate the substantial equivalence of the B-Capta to its predicate devices and is not included as part of this premarket notification.

Clinical testing was not required to demonstrate the substantial equivalence of the B-Capta to its predicate devices and is not included as part of this premarket notification.

VIII. CONCLUSION

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to predicate devices, B-Capta is substantially equivalent to its predicate devices.