May 24, 2024

Inspira Technologies Oxy B.H.N Ltd.
℅ Fernando Aguel
Vice President, Heart Failure & Circulatory Support Regulatory Affairs
MCRA
803 7th Street NW, 3rd Floor
Washington, District of Columbia 20005

Re: K232788
Trade/Device Name: Inspira Art100
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary bypass pump speed control
Regulatory Class: Class II
Product Code: DWA
Dated: April 22, 2024
Received: April 22, 2024

Dear Fernando Aguel:

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

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)*
K232788

Device Name
INSPIRA ART100

Indications for Use *(Describe)*
The INSPIRA ART100 system is intended for use in an extra corporeal perfusion circuit to pump blood during short duration cardiopulmonary bypass procedures lasting 6 hours or less.

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.

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510(K) SUMMARY

Inspira Technologies Oxy B.H.N. Ltd.'s INSPIRA™ ART100 Device

1. 510(k) Owner's Information:

Applicant's name: Inspira Technologies Oxy B.H.N. Ltd.
2 Ha-Tidhar St.,
Ra'anana, 4366504, Israel

Contact Person: Dganit Litinsky, VP RA
Tel. 972-9-9664488+
dganit@inspirao2.com

Date Prepared: September 11, 2023

2. Device Name

Trade Name: INSPIRA™ ART100

Common Name: Control, Pump Speed, Cardiopulmonary Bypass

Classification:

Product Code:	DWA
Regulation No:	21 C.F.R. §870.4380
Class:	Class: II, Cardiopulmonary bypass pump speed control
Classification Panel:	Cardiovascular

3. Predicate Device:

RotaFlow Centrifugal Pump System, cleared under K991864

4. Device Description:

The INSPIRA™ ART100 system is a device for pumping blood without direct contact in an extracorporeal blood circulation circuit. The device is prescribed (Rx) by specialists to be used in Cardiopulmonary Bypass (CPB) procedures.

The INSPIRA™ ART100 system consists of the following components:

1. Controller Unit
2. Pump Drive Unit
3. Manual Pump Drive Unit
4. Blood Flow and Bubble Detection Sensor
5. Temperature Sensor
6. Cable adapters for Pressure Sensors
7. Cable adapters for Temperature Sensor
8. Oxygenator and Pump Drive Holders

The system is compatible with a Non-Roller Centrifugal Pump (Capiox iCP Centrifugal Pump). The Inspira Pump Drives are magnetically coupled exclusively with the Capiox iCP Centrifugal Pump, designed and manufactured by Terumo Cardiovascular Systems Corporation, and can be supplied by Inspira.

The INSPIRA™ ART100 system is intended to be used in conjunction with other previously 510(k)-cleared devices and sterile accessories such as cannulas, catheters, oxygenators, luer connectors, pressure sensors, supplied by hospital users or other manufacturers. Those disposables are currently not supplied by Inspira as part of the system.

5. Intended Use / Indications for Use

The INSPIRA™ ART100 System is intended for use in an extracorporeal perfusion circuit to pump blood during short duration cardiopulmonary bypass procedures lasting six hours or less.

Contraindications

The INSPIRA™ ART100 system is contraindicated for use in a transport environment (aircraft, ambulance, etc.).
Contraindications of the disposables, as stated in their respective Instructions for Use, must be taken into account.

6. Intended Users

The INSPIRA™ ART100 system is designed for use by licensed physicians and perfusionists to perform cardiopulmonary bypass procedures. Trained specialists, surgical nurses and physician assistants may assist in the setup of the equipment and preparation of patients.

7. Intended Patient Population and Intended Part of Body

The device is intended to be used for patients needing cardiopulmonary bypass. Suitability of the device for specific patients is determined by licensed and trained physicians and specialists.

8. Intended Use Environment

The INSPIRA™ ART100 system is intended to be used in an operating room, and placed outside a sterile field.
The device is supplied non-sterile.

9. Technological Characteristics

The intended use and technological characteristics are compared with one predicate, legally marketed device and one reference device in the table below.

Product Name and Model	**INSPIRA™ ART100**	**Rotaflow® Centrifugal Pump System (Predicate)**	**Anivia SG1000 Pump Console (Reference)**	**Comparison/ Notes**
Manufacturer	Inspira Technologies Oxy B.H.N. Ltd.	Getinge Maquet Cardiopulmonary AG, Germany	APMTD Inc. USA	N/A
FDA 510(k) number	K232788	K991864	K221491 K230698	N/A
Indications for Use	The INSPIRA™ ART100 System is intended for use in an extracorporeal perfusion circuit to pump blood during short duration cardiopulmonary bypass procedures lasting six hours or less.	The RotaFlow Centrifugal Pump System is intended for use in an extracorporeal perfusion circuit to pump blood during short duration cardiopulmonary bypass procedures lasting six hours or less.	The Anivia SG1000 Pump Console is intended to pump blood through the extracorporeal bypass circuit for extracorporeal support for periods appropriate to cardiopulmonary bypass (up to 6 hours).	Same as predicate
FDA Classification Codes	Class II, CFR 870.4380, DWA, Cardiopulmonary bypass pump speed control	Class II, CFR 870.4360, KFM Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type	Class II, CFR 870.4380, DWA, Cardiopulmonary bypass pump speed control	Same as reference
Duration of Use	Up to 6 hours	Up to 6 hours	Up to 6 hours (limited by disposables, not limited by Console electro-mechanical modules)	Same as predicate.
Intended Use	Pump Speed Control, CPB Machine Console (not including sterile, blood-contacting accessories)	Pump Speed Control, CPB Machine Console (bundled with sterile, blood-contacting accessories, outside the scope of this application)	Pump Speed Control, CPB Machine Console (not including sterile, blood-contacting accessories)	Same as reference.
Intended Users	Cardiopulmonary physicians, perfusionists, trained physician assistants	Cardiopulmonary physicians, perfusionists, trained physician assistants	Cardiopulmonary physicians, perfusionists, trained physician assistants	Same as predicate.
Intended Patients	As prescribed by cardiopulmonary specialists	As prescribed by cardiopulmonary specialists	As prescribed by cardiopulmonary specialists	Same as predicate.

Product Name and Model	**INSPIRA™ ART100**	**Rotaflow® Centrifugal Pump System (Predicate)**	**Anivia SG1000 Pump Console (Reference)**	**Comparison/ Notes**
Identification of Disposable Centrifugal Pump Heads Compatible with System Console	Terumo Cardiovascular System Corporation, Capiox iCP Centrifugal Pump	RotaFlow® RF-32 centrifugal pump heads	Medtronic BPX-80, BP-50 centrifugal pump heads (w/ Pump Driver Module SG1000-PDM-001) RotaFlow® RF-32 centrifugal pump heads (w/ Pump Driver Module SG1000-PDM-002) Medtronic Affinity CPAP40, BBAP40, centrifugal pump heads (w/ Pump Driver Module SG1000-PDM-003) LivaNova Revolution® Catalogue No. 050300700, 050300000 centrifugal pump heads (w/ Pump Driver Module SG1000-PDM-004)	Same as predicate and reference. INSPIRA ART100 is following Anivia SG1000 precedent for clearing console with pump head from different manufacturer
Centrifugal Pump Driver	Non-contact, magnetically coupled	Non-contact, magnetically coupled	Non-contact, magnetically coupled	Same as predicate.
Regulation Control Functions	• Speed Regulation Mechanical Knob and Touch Display	• Speed Regulation • Flow Regulation (Stability) Mechanical Knob	• Speed Regulation • Flow Regulation (Stability) Mechanical Knob and Touch Display	No Flow Regulation – Difference has no impact on safety or effectiveness.
Components	• Controller • Pump Drive • Emergency Manual Pump Drive.	• Rotaflow Console • Pump Drive. • Emergency Handcrank.	• Touch screen control and display panel	Same as predicate.

Product Name and Model	**INSPIRA™ ART100**	**Rotaflow® Centrifugal Pump System (Predicate)**	**Anivia SG1000 Pump Console (Reference)**	**Comparison/ Notes**
	• Flow and Bubble Sensor • Integrated two Backup Batteries • Adjustable Support Holders	• Integrated flow and bubble sensors in the drive unit • Integrated battery backup • Adjustable Support Arm.	• Pump Driver Module • Emergency Handcrank • Flow Bubble Sensor • Backup Battery Module • Mobile cart with adjustable Support Arm (optional accessory) • Backup Pump Driver Module	
Pump Speed (RPM)	0 – 3600	0 – 5000	0 – 4500 0 – 5000 0 – 4000 0 – 3500	Centrifugal Pump Dependent. Difference has no impact on safety or effectiveness.
Visual and Auditory Alarms on Abnormal Conditions	Yes, preset limits: Speed Rate, Back Flow, Bubble, Pressure, Temperature.	Yes, preset limits	Yes, preset limits: Speed, Flow Rate, Back Flow, Bubble, Pressure, Temperature	Same as predicate.
Blood Flow Rate (L/min)	Dependent on external circuit, up to 0-8 L/min	Dependent on external circuit, up to 0 – 9.9 L/min	Dependent on external circuit, up to 0 – 9.9 L/min	Centrifugal Pump Dependent. Difference has no impact on safety or effectiveness.
Interface to Blood Flow Sensor	Yes (Qty 1)	Yes (Qty 1)	Yes (Qty 1)	Same as predicate.
Air Bubble Detector	Yes (Qty 1), integrated with Blood Flow Sensor.	Yes (Qty 1)	Yes (Qty 1), integrated with Blood Flow Sensor.	Same as reference.
Blood Flow and Bubble Detector Sensor Technology	Non-contact, ultrasound Clamp-On around blood tube.	Non-contact, ultrasound Clamp-On. around blood tube	Non-contact, ultrasound Clamp-On around blood tube	Same as predicate.

Product Name and Model	**INSPIRA™ ART100**	**Rotaflow® Centrifugal Pump System (Predicate)**	**Anivia SG1000 Pump Console (Reference)**	**Comparison/ Notes**
Pressure Sensors	Yes (Qty 3, external), previously 510(k) cleared accessories manufactured by third parties.	N/A	Yes (Qty 2, external), previously 510(k) cleared accessories manufactured by third parties	Difference has no impact on safety or effectiveness.
Temperature Sensors	Yes (Qty 1, external)	N/A	Yes (Qty 2, external), previously 510(k) cleared accessories manufactured by third parties.	Difference has no impact on safety or effectiveness
Power Input	100-240 VAC 50 – 60 Hz 4.0A – 1.8A 410 W	Factory Set 100/115/230/240 V AC 2A / 1A	Universal 90-264 VAC/50 – 60 Hz 2.5A / 1.3A up to 250 W	Difference has no impact on safety or effectiveness.
Backup Battery	Li Ion	NiCad	LiFePO4	Difference has no impact on safety or effectiveness.
Backup Battery Capacity	28.8 V 9.8 Ah, 282 WH, 2 hours, at 3600 RPM, 8 L/min 4 hours, at 2900 RPM, 8 L/min	24 VDC, 5 AH, 120 WH 1.5 hours, at 5 L/min	25.6 VDC, 12 AH, 307 WH, minimum 1 hour, up to 3 hours depending on speed and flow	Difference has no impact on safety or effectiveness.
Backup Pump	Yes, hand-crank	Yes, hand-crank	Yes, backup electrical Pump Driver Module on standby, and hand-crank	Same as predicate.
Pump Motor Technology	Brushless DC motor	Brushless DC motor	Brushless DC motor	Same as predicate.
Display Screen	13.3” FHD Color TFT-LCD	None	31 cm (12.1”)	Difference has no impact on safety or effectiveness.
Dimensions, Display & Control Module	33.00 cm W x 23.4 cm H x 44.8 cm D	18 x 39 x 24 cm	14 cm W x 15 cm H x 9 cm D	Difference has no impact on safety or effectiveness.
Weight, Display & Control	12 kg – including backup battery	14.4 kg including backup battery	3.3 kg – Display & Control Module	Difference has no impact on

Product Name and Model	INSPIRA™ ART100	Rotaflow® Centrifugal Pump System (Predicate)	Anivia SG1000 Pump Console (Reference)	Comparison/ Notes
	Difference has no impact on safety and effectiveness.		4 kg – Backup Battery Module	safety or effectiveness.
Automatic Pump Stop intervention	Yes, at bubbles detection. Indicated on screen via an Alarm and icon.	Yes, at bubbles detection (In Speed Regulation operation) Indicated via LED.	N/A	Same as predicate.
Operation Temperature Relative Humidity Pressure	 10-35°C 15-90% 70-106kPa	 10-40°C 15-95% 66-106kPa	N/A	Difference has no impact on safety or effectiveness.
Storage Temperature Relative Humidity Pressure	 (-20)-55°C 10-90% 50-106kPa	 (-18)-45°C 10-96% 66-106kPa	N/A	Difference has no impact on safety or effectiveness.

Centrifugal Pump Specifications (Compatible Device)

Product Name and Model	INSPIRA™ ART100	Capiox iCP Centrifugal Pump with Xcoating™ (Compatible Device)	Comparison/ Notes
Manufacturer	Inspira Technologies Oxy B.H.N. Ltd.	Terumo Cardiovascular Systems Corporation	N/A
FDA 510(k) number	K232788	K200091	N/A
Indications for Use	The INSPIRA™ ART100 System is intended for use in an extracorporeal perfusion circuit to pump blood during short duration cardiopulmonary bypass procedures lasting six hours or less.	The Capiox iCP Centrifugal Pump with Xcoating™ is a sterile, single use device, used as an extracorporeal blood pump for use in cardiopulmonary bypass procedures for up to 6 hours.	N/A
FDA Classification Codes	Class II, CFR 870.4380, DWA, Cardiopulmonary bypass pump speed control	Class II, CFR 870.4360, KFM Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type	N/A
Duration of Use	Up to 6 hours	Up to 6 hours	Same as Compatible Device

Product Name and Model	**INSPIRA™ ART100**	**Capiox iCP Centrifugal Pump with Xcoating™ (Compatible Device)**	**Comparison/ Notes**
Centrifugal Pump Driver	Non-contact, magnetically coupled	Non-contact, magnetically coupled	Same as Compatible Device
Pump Speed (RPM)	0 – 3600	0 – 3600	Same as Compatible Device
Blood Flow Rate (L/min)	Dependent on external circuit, up to 0-8 L/min	up to 0-8 L/min	Same as Compatible Device

The technological characteristics of the INSPIRA™ ART100 system are substantially the same as predicate device and where there are minor differences they do not raise different questions of safety and effectiveness.
The geometry and design parameters are consistent with the device's intended use as an electromechanical pump driver and controller in cardiopulmonary bypass procedures.

A. Pump Drive Module is based on a brushless DC motor, motor control electronics, and a contactless magnetic coupler driving a detachable one-time use centrifugal pump.
B. Manual Pump Drive is based on a transmission gear, connected from the "low gear side" to a crank handle, and from the "fast gear side" to a contactless magnetic coupler driving a detachable one-time use centrifugal pump.
C. Display & Control Module is based on a touch screen, a rotary knob, control electronics, isolated electronic signal interface for external sensors (accessories), and a medical grade AC-to-DC power supply.
D. Blood Flow Bubble Sensor Module is clamp-on non-contact ultrasonic flow meter, compatible with commonly used plastic blood tubes of specified diameters and material.
E. Two Backup Battery Modules are based on lithium ion that can provide at least 2 to 5 hours (load dependent) of backup power in case of brief power outage of the AC power line, or for supporting transport within a hospital.
F. The INSPIRA™ ART100 system may be used with the following previously 510(k) cleared devices, supplied by hospital users:
    - Blood pressure sensors, supplied sterile, Biometrix Ltd., Art-Line™ Disposable Pressure Transducer Set, as listed in the Instructions for Use.

9.1 Biocompatibility

Not applicable. The INSPIRA™ ART100 system does not contain any blood contacting or patient contacting devices. The INSPIRA™ ART100 is labeled for use with the Terumo Capiox iCP Centrifugal Pump with Xcoating™, previously cleared by the FDA in K200091.

9.2 Sterility and Shelf-Life

Not applicable. The INSPIRA™ ART100 system and accessories are provided non-sterile and have been tested with sterile, one-time use accessories/compatible devices specified in the Instructions for Use.

9.3 Non-Clinical Tests

The INSPIRA™ ART100 system performance characteristics were demonstrated through system bench testing, mechanical testing, electrical safety and electromagnetic interference and compatibility testing, software testing, reliability, and usability testing.

The following performance tests were conducted on the INSPIRA™ ART100 system to support the determination of substantial equivalence:

- Software verification and validation testing
- Functional design verification and validation testing
- Electrical safety, electromagnetic interference and compatibility (EMI/EMC) testing
- Interoperability evaluation with specified accessories/compatible devices
- Reliability testing
- Simulated use testing
- Cleaning validation
- Packaging and shipping testing

All testing met predetermined acceptance criteria.

The INSPIRA™ ART100 system was also tested and certified by accredited third party laboratories to meet the following consensus standards:

- IEC 60601-1:2020 (ed. 3.2) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

- IEC 60601-1-2:202020 (ed. 4.1) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

- IEC 60601-1-8:2020 (ed. 2.2) Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.

- IEC 62366-1:2020 (ed. 1.1) Medical devices - Part 1: Application of usability engineering to medical devices.

- IEC 60601-1-6: 2020 (ed. 3.2) Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.

- ISO 14971:2019 (ed 3.0) Medical devices - Application of risk management to medical devices
- IEC 62304:2006/AMD 1: 2015 (ed. 1.1) Medical device software - Software life cycle processes.
- IEC / UL 62133-2:2020 Ed.1 / CSA C22.2 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems.
- UN38.3, Seventh Edition United Nations Manual of Tests and Standards for the Transport of Dangerous Goods - Section 38.3 of Part 3 - Certification of Lithium Metal and Lithium-Ion Batteries.
- ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing.
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems, Assurance Level I, According to DC 2.
- ISO 17664-2:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices.

9.4 Animal Tests - Not Applicable

9.5 Clinical Tests - Not Applicable

9.6 Human Factors Testing

The INSPIRA™ ART100 System has completed a human factors validation study, in accordance with IEC 62366-1, ISO 14971 and FDA's latest guidance 'Applying Human Factors and Usability Engineering to Medical Devices.' All residual use-error risks were evaluated and minimized, and benefit/risk considerations were taken, to support the conclusion that no further changes to the user interface are necessary for safe device use and that the overall residual risk is acceptable. Inspira has concluded that the INSPIRA™ ART100 System is as safe and effective for the intended users, uses, and use environments as the predicate.

9.7 Labeling

The labeling includes instructions on circuit setup, explanation of the hardware and software user interface, visual and auditory alarms, maintenance during a procedure, precautions and warnings, troubleshooting guide, and performance characteristics relevant to compatibility among different devices and accessories in the circuit.

10. Conclusion

Based on the above comparisons of intended use, intended users, use environment, indications for use, operating principles, technological characteristics, performance test data, and compliance with the listed consensus standards, the INSPIRA™ ART100 is substantially equivalent to, and as safe and effective as the predicate device, the RotaFlow Centrifugal Pump System device previously cleared under K991864.