April 18, 2023

AMPTD Inc.
John Sasso
Director of Projects and Programs
226 Lowell Street, Unit B16
Wilmington, Massachusetts 01887

Re: K230698
Trade/Device Name: Anivia SG1000 Pump Console
Regulation Number: 21 CFR 870.4380
Regulation Name: Cardiopulmonary Bypass Pump Speed Control
Regulatory Class: Class II
Product Code: DWA
Dated: March 7, 2023
Received: March 13, 2023

Dear John Sasso:

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,

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

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)*
K230698

Device Name
Anivia SG1000 Pump Console

Indications for Use *(Describe)*

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).

Contraindications:

The Anivia SG1000 Pump Console is contraindicated as a cardiotomy suction device.

It is the responsibility of the physician to determine whether any physical impairment of the patient or associated equipment would contraindicate the use of this device.

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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Asia Pacific Medical Technology Development

K230698
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510(k) Summary of Safety and Effectiveness as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which Substantial Equivalence is based

1. 510(k) Owner's Information

510(k) Owner's Name: APMTD Inc.
Address: 226 Lowell Street, Unit B16
Wilmington, MA 01887
USA
Telephone: 1-949-623-8403

Contact Information: John Sasso
Director of Projects and Programs
Telephone: 781-962-6274
Email: jsasso@apmtd.us

Date Prepared: March 7, 2023

2. Device Name

Trade Name: Anivia SG1000 Pump Console

Common Name: Pump Console, Cardiopulmonary Bypass, Heart-Lung Machine,

Classification: 870.4380, Class II Cardiopulmonary bypass pump speed control

Product Code: DWA

3. Predicate Device:

Anivia SG1000 Pump Console, K221491, APMTD, Inc. (DWA)

4. Device Description

The Anivia SG1000 Pump Console 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 Anivia SG1000 Pump Console consists of the following modules:

Modules	Catalog Reference Number	Part Number
Display & Control Module	Anivia SG1000-DCM-001	CS-0510-ASY-00001
Pump Driver Module	Anivia SG1000-PCM-001	CS-0210-ASY-00002
	Anivia SG1000-PCM-002	CS-0210-ASY-00010
	Anivia SG1000-PCM-003	CS-0210-ASY-00015
	Anivia SG1000-PCM-004	CS-0210-ASY-00025

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Flow Bubble Sensor Module	Anivia SG1000-FBS-001	CS-0410-ASY-00001
	Anivia SG1000-FBS-002	CS-0410-ASY-00002
Backup Battery Module	Anivia SG1000-BBM-001	CS-0710-ASY-00001
Cart Module	Anivia SG1000-CRT-001	CS-0810-ASY-00001

The Anivia SG1000 Pump Console is intended to be used in conjunction with other previously 510(k)-cleared devices and sterile accessories such as cannulas, catheters, oxygenators, luer connectors and single use centrifugal pump heads, supplied by hospital users or other manufacturers.

5. Indications for Use

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).

Contraindications:

The Anivia SG1000 Pump Console is contraindicated as a cardiotomy suction device.

It is the responsibility of the physician to determine whether any physical impairment of the patient or associated equipment would contraindicate the use of this device.

6. Intended Users

The Anivia SG1000 Pump Console is designed for use by licensed physicians and specialists to perform cardiopulmonary bypass procedures. Trained perfusionists, 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 Anivia SG1000 Pump Console is intended to be used in an operating room, a cardiac catheterization laboratory, in an intensive care unit, 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.

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Product Name and Model	**Anivia SG1000 Pump Console**	**Anivia SG1000 Pump Console**
Manufacturer	APMTD Inc. USA	APMTD Inc. USA
FDA 510(k) number	K230698	K221491
Indications for Use	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).	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).
FDA Classification Codes	Class II, CFR 870.4380, DWA, Cardiopulmonary bypass pump speed control	Class II, CFR 870.4380, DWA, Cardiopulmonary bypass pump speed control
Duration of Use	Up to 6 hours (limited by disposables, not limited by Console electro-mechanical modules)	Up to 6 hours (limited by disposables, not limited by Console electro-mechanical modules)
Intended Use	Pump Speed Control, CPB Machine Console (not including sterile, blood-contacting accessories)	Pump Speed Control, CPB Machine Console (not including sterile, blood-contacting accessories)
Intended Users	Cardiopulmonary physicians, perfusionists, trained physician assistants	Cardiopulmonary physicians, perfusionists, trained physician assistants
Intended Use Environment	Cardiopulmonary procedure rooms, intensive care units	Cardiopulmonary procedure rooms, intensive care units
Intended Patients	As prescribed by cardiopulmonary specialists	As prescribed by cardiopulmonary specialists
Compatible Disposable 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)	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)

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Product Name and Model	**Anivia SG1000 Pump Console**	**Anivia SG1000 Pump Console**
	LivaNova Revolution® Catalog No. 050300700, 050300000 centrifugal pump heads (w/Pump Driver Module SG1000-PDM-004)	
Centrifugal Pump Driver	Non-contact, magnetically coupled	Non-contact, magnetically coupled
Control Function	• Speed Control • Flow Control (Stability) Mechanical Knob and Touch Display	• Speed Control • Flow Control (Stability) Mechanical Knob and Touch Display
Components	• Pump Driver Module • Touch screen control and display panel • Flow Bubble Sensor • Backup Battery Module • Mobile cart with adjustable Support Arm (optional accessory) • Backup Pump Driver Module • Emergency Handcrank	• Pump Driver Module • Touch screen control and display panel • Flow Bubble Sensor • Backup Battery Module • Mobile cart with adjustable Support Arm (optional accessory) • Backup Pump Driver Module • Emergency Handcrank
Pump Speed (RPM)	0 – 4500 for CS-0210-ASY-00002 (Medtronic BPX-80 compatible Pump Driver Module) 0 – 5000 for CS-0210-ASY-00010 (Maquet Rotaflow® RF-32 compatible Pump Driver Module) 0 – 4000 for CS-0210-ASY-00015 (Medtronic Affinity CP compatible Pump Driver Module) 0 – 3500 for CS-0210-ASY-00025 (LivaNova Revolution® compatible Pump Driver Module)	0 – 4500 for CS-0210-ASY-00002 (Medtronic BPX-80 compatible Pump Driver Module) 0 – 5000 for CS-0210-ASY-00010 (Maquet Rotaflow® RF-32 compatible Pump Driver Module)
Visual and Auditory Alarms on Abnormal Conditions	Yes, preset limits: Speed, Flow Rate, Back Flow, Bubble, Pressure, Temperature	Yes, preset limits: Speed, Flow Rate, Back Flow, Bubble, Pressure, Temperature

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Product Name and Model	**Anivia SG1000 Pump Console**	**Anivia SG1000 Pump Console**
Blood Flow Rate (L/min)	Dependent on external circuit, up to 0 – 9.9 L/min	Dependent on external circuit, up to 0 – 9.9 L/min
Interface to Blood Flow Sensor	Yes (Qty 1)	Yes (Qty 1)
Air Bubble Detector	Yes (Qty 1), integrated with Blood Flow Sensor	Yes (Qty 1), integrated with Blood Flow Sensor
Blood Flow and Bubble Detector Sensor Technology	Non-contact, ultrasound Clamp-On around blood tube	Non-contact, ultrasound Clamp-On around blood tube
Pressure Sensors	Yes (Qty 2, external), previously 510(k) cleared accessories manufactured by third parties	Yes (Qty 2, external), previously 510(k) cleared accessories manufactured by third parties
Temperature Sensors	Yes (Qty 2, external), previously 510(k) cleared accessories manufactured by third parties	Yes (Qty 2, external), previously 510(k) cleared accessories manufactured by third parties
Power Input	Universal 90-264 VAC/50 – 60 Hz 2.5A / 1.3A up to 250 W Same as predicate – single universal power supply, instead of different models, no effect on safety and effectiveness.	Universal 90-264 VAC/50 – 60 Hz 2.5A / 1.3A up to 250 W Same as predicate – single universal power supply, instead of different models, no effect on safety and effectiveness.
Backup Battery	LiFePO4	LiFePO4
Backup Battery Capacity	25.6 VDC, 12 AH, 307 WH, minimum 1 hour, up to 3 hours depending on speed and flow	25.6 VDC, 12 AH, 307 WH, minimum 1 hour, up to 3 hours depending on speed and flow
Backup Pump	Yes, backup electrical Pump Driver Module on standby, and hand-crank	Yes, backup electrical Pump Driver Module on standby, and hand-crank

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Product Name and Model	**Anivia SG1000 Pump Console**	**Anivia SG1000 Pump Console**
Pump Motor Technology	Brushless DC motor	Brushless DC motor
Display Screen	31 cm (12.1”)	31 cm (12.1”)
Dimensions, Display & Control Module	14 cm W x 15 cm H x 9 cm D	14 cm W x 15 cm H x 9 cm D
Dimensions, Pump Driver Module	Maximum Diameter: 113 mm, Height: 170 mm	Maximum Diameter: 113 mm, Height: 170 mm
Weight	3.3 kg – Display & Control Module 4 kg – Pump Driver Module 4 kg – Backup Battery Module	3.3 kg – Display & Control Module 4 kg – Pump Driver Module 4 kg – Backup Battery Module

The technological characteristics of the Anivia SG1000 Pump Console device 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 electro-mechanical pump driver and controller in cardiopulmonary bypass procedures.

A. Pump Driver 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. Display & Control Module is based on a video display, 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.

C. 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.

D. Backup Battery Module is based on lithium iron phosphate ($LiFePO_4$) chemistry that can provide at least 60 minutes of backup power in case of brief power outage of the AC power line, or for supporting transport within a hospital.

Not included in this Special 510(k) application are the following accessories:

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E. Cart Module (optional, supplied by Company, Product Code BZN, Class I, 510(K) Exempt) is a hand cart for mounting the Display & Control Module, the Pump Driver Module, the Flow Bubble Sensor Module, and the Backup Battery Module. The cart also provides a simple work surface, a storage bin, two IV poles, a holder for a gas cylinder, and locking caster wheels.

F. The Anivia SG1000 Pump Console may be used with the following previously 510(k) cleared devices, supplied by hospital users:

   a. Blood pressure sensors, supplied sterile, resistive bridge type that complies with ANSI/AAMI BP-22, 1994 and IEC 60601-2-34:Ed.3.0 standards, as listed in the Instructions for Use
   b. Temperature Sensors, supplied sterile, that meets YSI-400 and ISO 80601-2-56:2017 standards, as listed in the Instructions for Use
   c. One time use centrifugal pump heads, supplied sterile, as listed in the Instructions for Use

9.1. Biocompatibility

Not applicable. The Anivia SG1000 Pump Console does not contain any blood contacting or patient contacting devices.

9.2. Sterility and Shelf-Life

Not applicable. The Anivia SG1000 Pump Console and accessories are provided non-sterile and have been tested with sterile, one-time use accessories specified in the Instructions for Use.

9.3. Non-Clinical Tests

The Anivia SG1000 Pump Console 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 Anivia SG1000 Pump Console 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
- Reliability testing
- Simulated use testing
- Cleaning validation
- Packaging and ship testing

All testing met predetermined acceptance criteria.

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The Anivia SG1000 Pump Console was also tested and certified by accredited third party laboratories to meet the following consensus standards:

- IEC 60601-1:2005/AMD1:2012
- IEC 60601-1-2:2014
- IEC 60601-1-6:2010/AMD1:2013
- IEC 60601-1-8:2006/AMD1:2012
- ISO 80601-2-56:2017/AMD1:2018
- IEC 60601-2-34:2011
- IEC 80601-2-49:2018
- ISO 14971:2019
- IEC 62304:2006/AMD 1: 2015
- IEC 62366:2015
- UL 2054:2004 R9.11
- IEC 62133-2:2017/AMD1:2021
- UN38.3, Seventh Edition
- ASTM D4169:2022, DC13, Level I
- ISO 17664-2:2021

9.4. Clinical Tests

Not Applicable

9.5. 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, trouble shooting guide, and performance characteristics relevant to compatibility among different devices and accessories in the circuit.

10. Conclusions

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 Anivia SG1000 Pump Console is as safe and effective as the predicate device, the Anivia SG1000 Pump Console (K221491).