April 1, 2021

Eurosets S.r.l.
Katia Vescovini
RA/QA/CQ Manager
Strada Statale 12, n°143
Medolla, Modena i-41036
Italy

Re: K202206
Trade/Device Name: AMG PMP Pediatric
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: March 1, 2021
Received: March 4, 2021

Dear Katia Vescovini:

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)*
K202206

Device Name
AMG PMP PEDIATRIC

Indications for Use *(Describe)*
The device is indicated for patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for six hours or less with a maximum blood flow rate of 4 liters/minute.
PATIENT POPULATION: Pediatric / small adults.

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

1. General Information

Submitter:

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Fax +39 0535 51248

Establishment Registration Number: 3003752502

Contact:

Dr. Katia Vescovini
Tel.: +39 0535 660311
Email: kvescoviniregulatory@eurosets.com

Summary Preparation Date: March 31. 2021

2. Name & Classification

Device Name:	AMG PMP PEDIATRIC
Regulation Name:	Cardiopulmonary bypass oxygenator
Regulation Number:	870.4350
Product Code:	DTZ
CLASS:	II

3. Predicate Devices

The AMG PMP PEDIATRIC device is substantially equivalent to the following devices:

Applicant	Device name	510(k) Number
Sorin Group Italia S.r.l.	EOS PMP, EOS PMP Integrated	K150489 Primary predicate Dev.
Eurosets	A.M.G. MODULE PMP NO T.P. STERILE	K141492

4. Indications for Use

The device is indicated for patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for six hours or less with a maximum blood flow rate of 4 liters/minute.

PATIENT POPULATION: Pediatric / small adults.

5. Device Description

AMG PMP PEDIATRC is an oxygenator used to exchange gases between blood and gaseous environment to satisfy the gas exchange needs of a patient during open-heart surgery. It is composed by PMP (Polymethylpentene) hollow fiber membrane with an integrated heat exchanger. It is provided together with the accessories that are the gas line and the convenience kit.

Oxygenator module, AMG PMP PEDIATRIC consist of three pathways: gas path, blood path, water path. These three paths, thanks to the particular configuration, allow the blood temperature control and gas exchange. The device center consists stainless steel tubes that allow the control of the temperature of the blood. The exchange of heat is between the water (with controlled temperature) that flows outside of steel tubes and the blood that flows inside the steel tubes. The device is surrounded by an outer compartment that contains a microporous membrane of Polymethylpentene (PMP) consisting of capillary allow fibers that allows gas exchange. The air from the gas mixer is rich in O_2 and follows the gas path. It enters through the gas inlet port on the top of the device, goes through microporous PMP fibers and exits from gas escape port, at the same time blood flows outside the microporous fibers. The design of heat exchangers for cooling and rewarming blood in the oxygenator utilizes a biologically inert surface to achieve the desired rate of heat exchange without producing any localized overheating of the blood.

6. Comparison with the predicate devices

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	SECONDARY PREDICATE DEVICE
MODEL NAME:	**AMG PMP PEDIATRIC**	**K150489** **EOS PMP**	**K141492** **A.M.G. MODULE PMP NO T.P. STERILE**
APPLICANT:	Eurosets S.r.l.	Sorin Group Italia S.r.l.	Eurosets S.r.l.
CLASSIFICATION			
CLASS:	**II**	**II**	**II**
REGULATION NUMBER:	**870.4350**	**870.4350**	**870.4350**
PRODUCT CODE	**DTZ**	**DTZ**	**DTZ**
REGULATION NAME:	**Cardiopulmonary Bypass Oxygenator**	**Cardiopulmonary Bypass Oxygenator**	**Cardiopulmonary Bypass Oxygenator**
INDICATIONS FOR USE & PATIENT POPULATION			
INDICATIONS FOR USE:	**The device is indicated for patients who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for six hours or less with a maximum blood flow rate of 4 liters/minute.**	The device is intended for use in patients who undergo **cardiopulmonary bypass surgery requiring extracorporeal circulation** with a maximum blood flow rate 5 liters/minute. It provides oxygenation and carbon dioxide removal from venous blood. The integrated heat exchanger provides blood temperature control and allows the use of hypothermia or aids in the maintenance of normothermia during surgery. The device is intended to be used **for 6 hours or less.**	Is intended in **surgical procedure requiring** extracorporeal gas exchange support and blood temperature control **for periods of up to 6 hours.** The advanced Membrane Gas Exchange for **extracorporeal circulation** is a microporous hollow-fiber oxygenator with an integral heat exchanger used to perform **cardiopulmonary bypass.** It includes a detachable 4.5 liter blood reservoir.
PATIENT POPULATION:	**Pediatric / small adults**	**Pediatric / small adults**	**Adults**
TECHNICAL FEATURES			
MIN BLOOD FLOW:	0,5l/min	0,5l/min	**1l/min**
MAX BLOOD FLOW:	4l/min	5l/min	**7l/min**
KIND OF FIBER OXYGENATOR:	**Polymethylpentene (PMP)**	**Polymethylpentene (PMP)**	**Polymethylpentene (PMP)**
MEMBRANE SURFACE AREA:	1,35m^2	1,4m^2	**1,81m^2**
HEAT EXCAHNGER:	**integrated**	**integrated**	**integrated**
HEAT EXHANGE SURFACE AREA:	**0,08m^2**	0,15m^2	**0,08m^2**
STATIC PRIMING VOLUME:	190ml	≤200ml	**220ml**
COATING:	**Phosphorylcholine**	**Phosphorylcholine**	**Phosphorylcholine**
Materials	Polycarbonate (PC) Polyurethane resin Stainless Steel Silicone Polyvinyl Chloride (PVC) Polypropylene (PP) High Density Polyethylene (HDPE) Low Density Polyethylene (LDPE) Thermoplastic Elastomer - Styrene-Ethylene-Butylene-Styrene (SEBS) Hydrophobic Acrylic Copolymer Acrylonitrile-Butadiene-Styrene (ABS) PolyTetraFluoroEthylene (PTFE)	Unknown	Polycarbonate (PC) Polyurethane resin Stainless Steel Silicone Polyvinyl Chloride (PVC) Polypropylene (PP) High Density Polyethylene (HDPE) Low Density Polyethylene (LDPE) Thermoplastic Elastomer - Styrene-Ethylene-Butylene-Styrene (SEBS) Hydrophobic Acrylic Copolymer Acrylonitrile-Butadiene-Styrene (ABS) PolyTetraFluoroEthylene (PTFE)
OXYGENATOR CONNECTIONS			
VENOUS INLET:	3/8" (9,53mm)	3/8" (9,53mm)	3/8" (9,53mm)
ARTERIAL OUTLET:	3/8" (9,53mm)	3/8" (9,53mm)	3/8" (9,53mm)
GAS INLET:	1/4" (6,35mm)	1/4" (6,35mm)	1/4" (6,35mm)

	SUBJECT DEVICE	PRIMARY PREDICATE DEVICE	SECONDARY PREDICATE DEVICE
MODEL NAME:	**AMG PMP PEDIATRIC**	**K150489** **EOS PMP**	**K141492** **A.M.G. MODULE PMP NO T.P. STERILE**
STANDARDS			
BIOLOGICAL STANDARDS:	ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing;	ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing;	ISO 10993-1 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing;
PRODUCT SPECIFIC STANDARDS:	Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff, November 13, 2000; ISO 7199:2016 Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators);	Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff, November 13, 2000	Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff, November 13, 2000;

As can be seen from the table in the underlined parts, the Indications for Use of the AMG PMP PEDIATRIC and the predicate devices (K150489, K141492) are fundamentally the same with only some additional details provided for the predicate devices that do not affect the intended use of the subject device.

7. Performance Data

A program of design verification and validation testing was performed according to the standards "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff, November 13, 2000"; and ISO 7199:2016 "Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)".
This design verification and validation testing and includes the following tests:

- Blood cell damage
- Gas transfer rate & pressure drop
- Blood pathway integrity
- Heat exchanger fluid pathway integrity
- Gas pathway integrity
- Blood volume capacity (static priming volume)
- Residual blood volume
- Blood pathway connectors (tensile strength test)
- Heat exchanger fluid pathway connectors
- Heat exchanger performance evaluation
- Gas pathway connectors integrity (tensile strength test)

8. Summary

Results of these performance tests allow to demonstrate that the subject device AMG PMP PEDIATRIC met the safety and performance requirements as per its indication for use and that AMG PMP PEDIATRIC subject device is substantially equivalent with the EOS PMP predicate devices, proving that the AMG PMP PEDIATRIC is as safe, as effective, and performs as well as the EOS PMP.