December 12, 2025

Eurosets S.R.L
% Sebastian Feye
Regulatory Consultant
Accurate Consultants Inc.
3234 Ibis Street
San Diego, California 92103

Re: K250821
Trade/Device Name: Horizon AF Plus System (Integrated A.L. One AF Plus OXYGENATOR and Horizon CVR) (US5300); A.L. One AF Plus OXYGENATOR (US5204); Horizon CVR (US5073)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR, DTM, DTN,
Dated: November 12, 2025
Received: November 12, 2025

Dear Sebastian Feye:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Meaghan Erlewein -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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250821

Device Name

Horizon AF Plus System (Integrated A.L. One AF Plus OXYGENATOR and Horizon CVR) (US5300)

Indications for Use *(Describe)*

HORIZON AF Plus is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control.
HORIZON AF Plus integrated arterial filter provides additional protection against air and solid emboli.
HORIZON AF Plus is intended to be used for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K250821

510(k) Summary

Prepared on: 2025-12-10

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Eurosets S.R.L
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Correspondent Contact	Mr. Sebastian Feye
Correspondent Contact Email	sebastian@accuratefdaconsulting.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Horizon AF Plus System (Integrated A.L. One AF Plus OXYGENATOR and Horizon CVR) (US5300)
Common Name	Cardiopulmonary bypass oxygenator
Classification Name	Cardiopulmonary bypass oxygenator
Regulation Number	870.4350
Product Code(s)	DTZ, DTR,DTM,DTN

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180448	Inspire 8F M Hollow Fiber Oxygenator with integrated AF	DTZ
K120185	LivaNova Inspire 6F hollow fiber oxygenator with integrated arteri	DTZ

Device Description Summary

21 CFR 807.92(a)(4)

The HORIZON AF PLUS System (Model number: US5300) is composed of the HORIZON ADULT OXYGENATOR with Integrated Arterial Filter Plus (A.L. One AF Plus) and the Horizon cardiotomy/venous reservoir (CVR).
The HORIZON ADULT OXYGENATOR with Integrated Arterial Filter Plus is a microporous hollow-fibre membrane oxygenator consisting of a gas exchange module with an integrated heat exchanger and an integrated 38µm arterial filter that ensures arterial blood filtration with removal of microaggregates and microemboli.
HORIZON AF PLUS also has a hard-shell cardiotomy/venous reservoir (CVR) integrated with two cardiotomy filters, designed to allow venous drainage of the patient's blood, both through the hydrostatic load (height difference between the patient and the reservoir) and

the vacuum-assisted venous drainage (VAVD) technique.
HORIZON AF PLUS inner contact surfaces are coated with A.G.I.L.E. (Advanced Generation Inert Layer E.C.C.) system, based on Phosphoriylcoline (PC).

The device is single use, non-pyrogenic, supplied STERILE and individually packed.
The device is individually packed and sterilized by ethylene oxide.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

HORIZON AF Plus is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. HORIZON AF Plus integrated arterial filter provides additional protection against air and solid emboli.
HORIZON AF Plus is intended to be used for 6 hours or less.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject and primary devices have the same intended use and are intended for use up to 6 hours.

Technological Comparison 21 CFR 807.92(a)(6)

The Horizon AF Plus System shares the same principle of operation and intended use as the predicate devices, with certain technological enhancements that optimize its performance. The differences related to those technological enhancements in the subject device are primarily in the material and technical specifications. These variations are due to design differences and have no material impact of the operation use and effectiveness of the subject device compared to the predicates.

Eurosets has demonstrated compliance for the Horizon AF Plus System with all relevant regulatory guidelines and industry standards, including specific FDA guidance for cardiopulmonary bypass oxygenators and ISO requirements for extracorporeal circuits. The testing methods employed are based on recognized industry standards, and all results meet predefined acceptance criteria that align with established safety and performance benchmarks.

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

The Horizon AF Plus System (Integrated A.L. One AF Plus Oxygenator and Horizon Cardiotomy/Venous Reservoir (CVR)) has undergone the appropriate nonclinical bench performance testing to determine its substantial equivalence to the predicate device. This testing was performed in accordance with the requirements established in the FDA "Guidance for Cardiopulmonary Bypass (CPB) Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff issued on: November 13, 2000", "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submissions; Final Guidance for Industry and FDA Document issued on: November 29, 2000" as well as the following standards: "ISO 7199:2016 Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)", "ASTM D4169 Packaging Configuration – Shipping Validation" and "ISO 15674:2016 "Cardiovascular implants and artificial organs – Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags".

The following non-clinical bench performance tests were completed and met all acceptance criteria or appropriate standard:

1. Blood cell damage
2. Gas transfer rate & blood pressure drop
3. Heat exchanger efficiency
4. Blood pathway integrity
5. Breakthrough volume
6. Dynamic hold-up (priming) volume
7. Blood volume capacity (static priming volume)
8. Venous filtration efficiency
9. Arterial filtration efficiency
10. Gas pathway integrity and heat exchanger fluid pathway integrity
11. Coating integrity, stability, and coverage testing
12. Verification of cardiotomy defoaming capacity per ISO 15674
13. Packaging configuration – shipping validation per ASTM D4169

The results of the nonclinical bench performance studies demonstrate that the Horizon AF Plus System performs in a manner substantially equivalent to the predicate device with regard to the relevant functional parameters. The cumulative test results provide substantial evidence that the device meets the parameters of the predicate device, maintains functional integrity under worst-case conditions, and fully complies with all applicable regulatory standards and guidelines. Additional testing demonstrated the Horizon AF Plus System is sterile and non-pyrogenic.