



November 24, 2025

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

Re: K242503

Trade/Device Name: Trilly Oxygenator with Integrated Arterial Filter and Hardshell Reservoir
(US5232)

Regulation Number: 21 CFR 870.4350

Regulation Name: Cardiopulmonary Bypass Oxygenator

Regulatory Class: Class II

Product Code: DTZ, DTN, DTM, DTR

Dated: November 10, 2025

Received: November 10, 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,

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

Indications for Use

Submission Number (if known)

K242503.S002

Device Name

Trilly Oxygenator with Integrated Arterial Filter and Hardshell Reservoir (US5232)

Indications for Use (Describe)

The Trilly Oxygenator with Integrated Arterial Filter and Hardshell Reservoir is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery.

The integrated arterial filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit. The integrated heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device.

The hardshell reservoir is used to store blood during extra-corporeal circulation from the venous line and the cardiotomy line. The reservoir contains a venous section that is compromised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal. The 2.5-liter reservoirs may be used for Vacuum Assisted Drainage procedures and Post-Operative Chest Drainage Procedures.

Trilly Oxygenator with Integrated Arterial Filter and Hardshell Reservoir is for use with patients when the required blood flow will not exceed 3.5 L/min and within a BSA range of 1.28 to 1.46.

Trilly Oxygenator with Integrated Arterial Filter and Hardshell Reservoir can be used in procedures lasting up to 6 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.

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Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

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Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	Trilly Oxygenator with Integrated Arterial Filter and Hardshell Reservoir (US5232)
Common Name	Cardiopulmonary bypass oxygenator
Classification Name	Cardiopulmonary bypass oxygenator
Regulation Number	870.4350
Product Code	DTZ

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K151389	Terumo Capiox FX15 Advance Oxygenator with Integrated Arterial Filter	DTZ

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The TRILLY OXYGENATOR with Integrated Arterial Filter and Hardshell Reservoir ("Trilly AF") 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 micro emboli.

The device also has a hard-shell cardiotomy/venous reservoir (CVR) that can be connected to the aspirators, designed to allow venous drainage of the patient's blood, making use of both the hydrostatic load offered by the difference in height between the patient and the reservoir and the vacuum-assisted technique (VAVD).

The device hard-shell cardiotomy/venous reservoir is fitted with a pressure relief valve.

The device inner contact surfaces are coated with A.G.I.L.E. (Advanced Generation Inert Layer E.C.C.) system, based on Phosphorylcholine (PC). The A.G.I.L.E. coating doesn't have any biological activity.

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

Intended Use/Indications for Use

[21 CFR 807.92\(a\)\(5\)](#)

The Trilly Oxygenator with Integrated Arterial Filter and Hardshell Reservoir is intended to be used to exchange gases between blood and a gaseous environment to satisfy the gas exchange needs of a patient during cardiopulmonary bypass surgery. The integrated arterial filter is intended to filtrate non-biologic particles and emboli and to facilitate air bubble removal from the blood flowing through the cardiopulmonary bypass circuit. The integrated heat exchanger is used to warm or cool blood and/or perfusion fluid as it flows through the device. The hardshell reservoir is used to store blood during extra-corporeal circulation from the venous line and the cardiotomy line. The reservoir contains a venous section that is compromised of a filter and defoamer to facilitate air bubble removal. The cardiotomy section of the reservoir contains a filter to remove particulate matter and a defoamer to facilitate air bubble removal. The 2.5-liter reservoirs may be used for Vacuum Assisted Drainage procedures and Post-Operative Chest Drainage Procedures. Trilly Oxygenator with Integrated Arterial Filter and Hardshell Reservoir is for use with patients when the required blood flow will not exceed 3.5 L/min and within a BSA range of 1.28 to 1.46. Trilly Oxygenator with Integrated Arterial Filter and Hardshell Reservoir can be used in procedures lasting up to 6 hours.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

The indication of use are similar, except that the proposed device has a reservoir 2.5L for the subject device, while the predicate device has a 3L and 4L reservoir.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

Both Cardiopulmonary Bypass (CPB) Oxygenators use the same regulatory name, regulatory code, regulatory classification and have the same Product Codes DTZ, DTN, DTR, DTM. Both the Trilly Oxygenator with Integrated Arterial Filter and Capiox® FX15 Advance Oxygenator have similar intended use statements and are intended for the same patient population (small adults). Both CPBs Oxygenators can be used in procedures for a maximum of 6 hours. Both CPB Oxygenators are for prescription use only. Both CPB Oxygenators have similar designs and consist of similar material composition of the main components like the Materials Housing, the filtering material and the potting material and both use an integrated stainless steel heat exchanger. Both the Trilly Oxygenator and the predicate device use Microporous polypropylene (PP) as the membrane material. Furthermore, both CPB Oxygenators utilize the same technologies and principles of operation. Additionally, both have the same minimum and oxygenator connection sizes. The O₂ and CO₂ transfer rate in mL/min is the same for both devices, and the heat exchanger efficiency is very comparable, with only a small variance of 0.8 vs 0.75 effectiveness. Both devices have undergone the same biocompatibility, performance testing and sterility validation to demonstrate substantial equivalence.

In terms of differences the subject device uses an Advance Generation Inert Layer ECC (A.G.I.L.E) phosphorylcholine (PC) coating, while the predicate device employs an Xcoating amphiphilic polymer surface coating. Eurosets A.G.I.L.E PC utilizes the predominant lipid headgroup found in the outer layer of cell membranes. PC has a natural affinity for water and binds water tightly around itself, demonstrating hydrophilic properties as water is attracted to the material. Compared to the Terumo Xcoating which is an amphiphilic polymer that has both hydrophobic and hydrophilic properties. Since both coating materials have hydrophilic properties and perform similarly in use, their differences have been determined to be not significant. The subject device has a smaller membrane surface area (1.10 m² vs 1.5 m²) and heat exchanger surface area (0.04 m² vs 0.14 m²). It also has a lower max blood flow (3.5 L/min vs 4.0 L/min) and static priming volume (130 ml vs 144 ml) but a larger integrated arterial filter size (80+38 microns vs 32 microns). The subject device's reservoir has a slightly higher minimum volume of 90 ml (verses 70 ml for the predicate device) as well as a lower maximum volume of 2,500 ml (verses 3,000 ml for the predicate device). In terms of performance, the subject device exhibits higher pressure drops at both 2 LPM (65 mmHg vs 40 mmHg) and at maximum flow rates (130 mmHg @ 3.5 L/min vs 80 mmHg @ 4 L/min), however some of this difference may be attributable due to the difference in flow rate of the subject and predicate devices (3.5 vs 4 LPM). Finally, the subject device shows a slightly higher heat exchanger efficiency at 2/10 LPM (0.8 vs 0.75).

Non-Clinical and/or Clinical Tests Summary & Conclusions

[21 CFR 807.92\(b\)](#)

The Trilly Oxygenator with Integrated Arterial Filter and Hard-shell Reservoir (Trilly AF) has undergone a program of design verification 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". Below is a brief discussion of the nonclinical tests, along with the

associated report numbers and standards used.

1. ISO 7199:2016 Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)

- Blood cell damage (Oxygenator & CVR): Blood cell damage testing was conducted separately on the Oxygenator and CVR in vitro on 5 subject devices and 5 predicate devices (Terumo Capiox FX15 K151389) over a testing period of 6 hours in accordance with ISO 7199:2016 and the FDA's 2000 CPB Guidance. Evaluation of the Plasma Free Hemoglobin (PFH), White Blood Cell (WBC) and Platelets (PLT) were calculated at each time point at the maximum blood and gas flow rates. All pre-established acceptance criteria were met and the blood cell damage behavior of both the subject devices and predicate devices can be considered substantially equivalent, with no deviations. The blood cell damage test report for the Oxygenator is documented in report TP_TR58-2023, and the report for the CVR is documented in report TP_TR92-2017.
 - Gas transfer rate & blood pressure drop: The gas transfer rate and pressure drop over operational variable settings (blood flow rate and gas flow rate) were evaluated over a 6-hour period on 5 subject devices and 5 predicate devices in accordance with ISO 7199:2016 standard and the FDA's 2000 CPB Guidance. Test results demonstrate that both gas transfer rates and pressure drops of subject device and predicate device are substantially equivalent. The test report for gas transfer rates and pressure drops is documented in TP_TR211-2022.
 - Blood pathway integrity (Oxygenator & CVR): The integrity of the blood pathway was tested to ensure the device did not leak under worst case conditions in accordance with ISO 7199:2016 standards and the FDA's 2000 CPB Guidance. Blood pathway integrity testing was performed on 5 Oxygenator device samples which have been subjected to positive pressure of 150 kPa (1.5 times of the recommended max pressure of 100 kPa) for 6 hours, and 5 CVR sample devices which have been subjected to the recommended max pressure of 7.9mmHg (1.5 the recommended max pressure of 5.3 mmHg) for a period of 6 hours. All samples were leak free, confirming the blood pathway integrity of the proposed device. The blood pathway integrity test report for the Oxygenator is documented in TP_TR57-2023, and the report for the CVR is documented in TP_TR157-2022.
 - Gas Pathway integrity and heat exchanger fluid pathway integrity (Oxygenator): The gas pathway and heat exchanger fluid pathway integrity testing were conducted only with the Oxygenator. Five (5) oxygenators were subject to 300 kPa (1.5 times recommended 200 kPa) for 6 hours to determine the heat exchanger fluid pathway integrity. An additional Five (5) oxygenators were subject to 150 mmH2O (1.5 times of the recommended max pressure of 100 mmH2O) for 10 minutes to test for gas pathway integrity. All 10 samples did not show leakages, confirming integrity of the device. The gas pathway and heat exchanger fluid pathway integrity test reports are documented in TP_TR57-2023.
 - Blood volume capacity (static priming volume): The blood volume capacity was tested in accordance with ISO 7199:2016 standard and the FDA's 2000 CPB Guidance. 5 device samples were weighed empty and after being filled with osmotized water to determine the blood volume capacity. Note for this test it is not possible to separate the oxygenating module from the heat exchanger in order to determine the priming volume because for their design as they are intrinsically linked. If the heat exchanger were separated from the oxygenating module to measure the priming volume, all the liquid would flow into the test area, and it would not be possible to perform the test. The results met all acceptance criteria. The blood volume capacity test report for the device is documented in TP_TR102-2022.
 - Filtration efficiency: The filtration efficiency of the oxygenator module with integrated arterial filter was determined and assessed in accordance with the ISO 7199:2016 standard. The filtration efficiency test report for the device is documented in TP_TR83-2017.
 - Residual blood volume: The residual blood volume in the CVR was determined in accordance with both the ISO 7199:2016 standard and FDA 2000 CPB Guidance. For over 15 minutes, five (5) device samples reservoirs were filled with osmotized water to simulate the maximum blood volume that could be in the device, then the reservoirs were completely drained over 15 minutes. The amount of volume of total collected blood is then subtracted from the maximum filling volume of the reservoir to calculate the blood rest volume or static residual volume that is not returned to the patient from the reservoir and which remains in the device. The residual blood volume report is documented in TP_TR160-2022. The accuracy of the graduate scale, the maximum operating volumes and blood rest are documented in test report PR_RP09 issued by Cardionova SRL & Eurosets SRL.
 - Blood pathways connectors and Gas Pathway connectors (tensile strength test): The blood and gas (inlet and outlet) pathway connectors were tested following ISO 7199 standards and the FDA's CPB Guidance. Six (6) devices were used for this testing, three (3) devices were tested right away for tensile strength at t=0 and three (3) devices were subject to accelerated aging (3.5 years) and then tested for tensile strength. At t=0, three of six (3/6) devices were subjected to axial tensile load of 15 N. Then at t=3.5 years accelerated, the other three of six (3/6) devices were subjected to axial tensile load of 15 N for a period of 15 seconds. All samples withstood the applied force without showing separations or breaks, meeting acceptance criteria and the standard requirements. The tensile strength test report is documented in TP_TR25-2017.
 - Heat exchanger performance evaluation: The performance of three (3) heat exchangers from three (3) production lots were evaluated to determine the heat exchanger performance factor in accordance with ISO 7199:2016 standard and the FDA's 2000 CPB Guidance. Result of this test demonstrated that all test samples met acceptance criteria and design input requirements. The heat exchanger performance test report is documented in TP_TR74-2017.
- ### 2. ASTM D4169: Packaging Configuration – Shipping Validation
- The packaging configuration of the device and its shipping and its ability to withstand shipping and handling were validated in accordance with ASTM D4169. The shipping validation reports were documented in TP_TR15_TR76-2022 Shipping Testing.
- ### 3. CVR Specific Testing - ISO 15674:2016 "Cardiovascular implants and artificial organs – Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags
- Verification of Dynamic Hold Up (priming) Volume over operational flow range: This test ensured the dynamic hold-up volume was within acceptable limits during operational flow ranges. This test report is documented in TP_TR75-2017.
 - Verification of air handling capability and determination of minimum operating volume over operational flow range: This test report is documented in TP_TR76-2017.

- Filtration Efficiency Test (Aged Samples): The aging test assessed the filtration efficiency over time, ensuring the device's filter longevity and reliability. This test report is documented in TP_TR19-2017.
- Verification of break through volume and apparition time: The cardiotomy defoaming break through volume and apparition time was verified to meet FDA guidelines. The results are documented in report TP_TR93-2017.
- Verification of cardiotomy defoaming capacity: The cardiotomy defoaming capacity was verified to meet FDA guidance. This test report is documented in TP_TR94-2017.

Note that the Trilly AF Oxygenator is not intended to be used as defoamer but only the polyurethane sponge is treated with a defoamer and it is tested to be in compliance with the requirement 'Defoaming characteristics' as per ISO 15764:2016 "Cardiovascular implants and artificial organs – Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags" § 4.3.4.8 (refer to TP_TR 94-2017 and TP_TR93-2017).

The appropriate tests were conducted adhering to recognized standards to ensure the safety, efficacy, and reliability of the Trilly AF Oxygenator. Furthermore, the subject device has been evaluated for biocompatibility in compliance with ISO 10993-1 requirements and sterilization has been validated in compliance to ISO 11135 and ISO 10993-7 standard. The results of these tests provide substantial evidence supporting the device's performance and its equivalence to the predicate device.

The Trilly AF demonstrated a high level of safety through passing various performance tests that the predicate device also conducted. The blood cell damage testing for both the oxygenator and CVR demonstrated that the blood cell damage behavior of the subject device is substantially equivalent to the predicate device. Gas transfer rate and blood pressure drop were evaluated over operational variable settings confirmed substantial equivalence in gas transfer rate and pressure drop. Blood pathway integrity confirmed no leakage, verifying the integrity of the devices. The integrity of the gas pathway and heat exchanger fluid pathway for the oxygenator was also verified. Device samples were subjected to pressures exceeding the recommended maximum, and all samples showed no leakage. The blood volume capacity (static priming volume) test confirmed compliance with pre-established acceptance criteria. Filtration efficiency and residual blood volume confirmed minimal residual blood volume, meeting acceptance criteria. Blood and gas pathway connectors were tested for tensile strength, with device samples withstanding applied axial tensile loads without separation or breakage, meeting standard requirements. The heat exchanger performance evaluation confirmed that all samples met acceptance criteria and design input requirements. Packaging configuration and its ability to withstand shipping and handling were validated according to ASTM D4169.

CVR-specific testing followed ISO 15674:2016 standards. Verification of dynamic hold-up volume, air handling capability, filtration efficiency (aged samples), breakthrough volume, and cardiotomy defoaming capacity all confirmed the CVR's performance and compliance with FDA guidelines.

The results from the nonclinical tests provide substantial evidence that the Trilly AF has met all the necessary safety and performance standards, supporting its substantial equivalence for FDA approval. Based on the results of all of the non-clinical testing, we conclude that the Trilly AF is as safe, as effective, and performs as well as the legally marketed predicate device Terumo Capiiox FX15.