November 1, 2023

Chalice Medical Ltd
Stephen Horan
Project Manager
Manton Wood Enterprise Park
Worksop, Nottinghamshire S80 2RS
United Kingdom

Re: K231414
Trade/Device Name: CMO8 Adult PMP Oxygenator with Tubing Pack (Model: CME40009)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary bypass oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR, DWF
Dated: September 24, 2023
Received: October 4, 2023

Dear Stephen Horan:

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)*
K231414

Device Name
CMO8 Adult PMP Oxygenator with Tubing Pack (Model: CME40009)

Indications for Use *(Describe)*
The CMO8 Adult PMP Oxygenator is a hollow fiber membrane oxygenator intended for physiologic gas exchange in adults and small adults undergoing cardiopulmonary bypass surgery. The integrated heat exchanger makes it possible to regulate the blood temperature. The CMO8 Adult PMP Oxygenator is intended for clinical use for up to 6 hours. The Tubing Pack is intended for use in extracorporeal circulation during 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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5. 510(k) Summary

Date Prepared:	20th September 2023
Submitter's Name and Address	Chalice Medical Ltd Manton Wood Enterprise Park, Worksop, Nottinghamshire, S80 2RS, United Kingdom
Contact Person:	Stephen Horan Project Manager, Chalice Medical Ltd Phone: +44 1909 470 777 Email: shoran@chalicemedical.com
Proprietary Name:	CMO8 Adult PMP Oxygenator with Tubing Pack (Model: CME40009)
Common Name:	Cardiopulmonary bypass tubing pack
Regulation Name:	Cardiopulmonary Bypass Vascular Catheter, Cannula or Tubing
Regulation Number:	870.4350, 870.4240, 870.4210
Product Code:	DTZ, DTR, DWF
Regulatory Class:	Class II
510(k) Review Panel	Cardiovascular
Predicate Devices	Paragon Adult Maxi PMP Oxygenator with Tubing Pack (K201642), MVR Venous Reservoir Bag (K920774)
FDA Clearance	TBC

5.1 Device Description

The CMO8 Adult PMP oxygenator (CMO8) is a hollow fiber membrane oxygenator with an integrated heat exchanger. The CMO8 facilitates the gas exchange into and out of the blood, and the regulation of blood temperature during cardiopulmonary bypass. The CMO8 is supplied with a Rheopak surface coating that reduces platelet adhesion to coated surfaces.

The gas exchanger part of the CMO8 is formed of plasma tight hollow fiber membranes. The gas flow takes place through the inner lumen of the fibers. Blood is in contact with the outer side of the membranes, so that oxygen can diffuse into the venous blood, while carbon dioxide diffuses out of the blood. The heat exchanging part of the CMO8 is made of non-porous hollow fiber membranes. Water flows through the inner lumen of the fibers, so that blood temperature flowing outside is regulated.

The Tubing Pack, which contains blood lines, gas lines, a venous reservoir and the CMO8 Oxygenator, is a component of a cardiopulmonary bypass procedure that facilitates extracorporeal circulatory support for a term of up to 6 hours.

5.2 Indications for Use

CMO8 Adult PMP Oxygenator with Tubing Pack (Model: CME40009)

The CMO8 Adult PMP Oxygenator is a hollow fiber membrane oxygenator intended for physiologic gas exchange in adults and small adults undergoing cardiopulmonary bypass surgery. The integrated heat exchanger makes it possible to regulate the blood temperature. The CMO8 Adult PMP Oxygenator is intended for clinical use for up to 6 hours. The Tubing Pack is intended for use in extracorporeal circulation during cardiopulmonary bypass procedures, lasting 6 hours or less.

5.3 Technological Characteristics

The CMO8, Tubing Pack and Venous Reservoir have been compared with the predicate devices and found to be substantially equivalent. The devices have the following similarities:

- Same intended use,
- Same operating principle,
- Same fundamental technological characteristics,
- Same biological status (i.e. sterile, non-pyrogenic),
- Same base materials,
- Same packaging materials and configurations,
- Same methods of sterilisation.

The CMO8 and the Tubing Pack are both single use disposable products, supplied sterile, sterilised by ethylene oxide, non-toxic and non-pyrogenic. The shelf life of the CMO8 Adult PMP Oxygenator and Tubing Pack have been substantiated using products that have been subjected to simulated distribution conditions and aged prior to performance testing.

5.4 In Vitro Test Results

Performance testing has been planned and conducted in accordance with the requirements of the following:

- FDA's Guidance for Cardiopulmonary Bypass Oxygenators (2000),
- ISO 7199:2016 Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators),
- ISO 15676:2016 Cardiovascular implants and artificial organs -- Requirements for single-use tubing packs for cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO),
- BS ISO 15674:2016+A1:2020 Cardiovascular implants and artificial organs – Hard-shell cardiotomy/venous reservoir systems (with and without filter) and soft venous reservoir bags.

The following performance characteristics were evaluated for the CMO8 oxygenator, Tubing Pack and Venous Reservoir:

Test	Method	Conclusion
Blood Pathway Integrity	Non-comparative	Acceptance criteria met by the devices.
Heat Exchanger Fluid Pathway Integrity	Non-comparative	Acceptance criteria met by the devices.
Gas Pathway Integrity	Non-comparative	Acceptance criteria met by the devices.
Connector security	Non-comparative	Acceptance criteria met by the devices.
Oxygen Transfer Rates	Comparative	No statistically significant difference in the O_2 transfer rates of the CMO8 oxygenator and the predicate.
Carbon Dioxide Transfer Rates	Comparative	No statistically significant difference in the CO_2 transfer rates of the CMO8 oxygenator and the predicate.
Blood Side Pressure Drop	Comparative	The CMO8 has a lower and more clinically favourable blood side pressure drop than the predicate oxygenator as a consequence of slight differences in the oxygenator design.
Heat Exchanger Performance Factor	Comparative	No statistically significant difference in the heat exchanger performance of the CMO8 oxygenator and the predicate.
Blood cell damage	Comparative	No statistically significant difference in the blood cell damage test results (e.g. hemolysis, white blood cell count, platelet

		count) of the CMO8 oxygenator and venous reservoir and their respective predicates.
Filtration efficiency	Non-comparative	Acceptance criteria met by the devices.
Air Handling Capacity	Comparative	No statistically significant difference in the air handling capacity performance of the venous reservoir and the predicate.
Blood Volumes and Dynamic prime volumes	Non-comparative	Acceptance criteria met by the devices.
Tubing kink resistance	Comparative	No statistically significant difference in the kink resistance of the Tubing Pack and the predicate tubing.
Tubing clamp resilience	Comparative	No statistically significant difference in clamp resilience of the Tubing Pack and the predicate tubing.
Pressure decay of tubing	Comparative	No statistically significant difference in the pressure decay of the Tubing Pack and the predicate tubing.

5.5 Non-Clinical Test Results

The biological safety of the CMO8 Oxygenator with Tubing Pack have been evaluated in accordance with the process defined in ISO 10993-1:2009. Biological risk assessments and the applicable biocompatibility testing demonstrate the biocompatibility and biological safety of these devices.

The CMO8 Oxygenator with Tubing Pack is sterilised by ethylene oxide gas to achieve a SAL of 10^{-6}. The pyrogen levels of the devices were determined following ANSI/AAMI ST72:2011 – Bacterial Endotoxins Test Methods, Routine Monitoring and Alternatives to Batch Testing. The Bacterial Endotoxin Testing validation confirmed that the endotoxin recoveries were all below the 'Endotoxin Release Limit' of <20 EU/device.

5.6 Conclusion

The information provided within this submission demonstrates that the CMO8 Adult PMP Oxygenator with and without Tubing Pack are substantially equivalent to the identified predicate devices.