February 28, 2020

Chalice Medical Ltd
Carol Middleton
Quality Manager
Manton Wood Enterprise Park,
Worksop, S80 2RS Gb

Re: K191246
Trade/Device Name: Paragon Adult Maxi PMP Oxygenator (Model: XCMOP405PMP)
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, DTR
Dated: January 2, 2020
Received: January 6, 2020

Dear Carol Middleton:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191246

Device Name
Paragon Adult Maxi PMP Oxygenator (Model: XCMOP405PMP)

Indications for Use *(Describe)*
The Paragon Adult Maxi 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 Paragon Adult Maxi PMP Oxygenator is intended for clinical use for 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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2. 510(k) Summary

Date Prepared:	21st February 2020
Submitter's Name and Address	Chalice Medical Ltd Manton Wood Enterprise Park, Worksop, Nottinghamshire, S80 2RS, United Kingdom
Contact Person:	Carol Middleton Quality Manager, Chalice Medical Ltd Phone: +44 1909 470 777 Email: cmiddleton@chalicemedical.com
Alternate Contact:	Stephen Horan Project Manager Phone: +44 1909 470 777 Email: shoran@chalicemedical.com
Proprietary Name:	Paragon Adult Maxi PMP Oxygenator (Model: XCMOP405PMP)
Common Name:	Hollow fiber membrane oxygenator with an integrated heat exchanger.
Regulation Name:	Cardiopulmonary Bypass Oxygenator
Regulation Number:	870.4350, 870.4240
Product Code:	DTZ, DTR
Regulatory Class:	Class II
510(k) Review Panel	Cardiovascular
Predicate Device	Sorin Group Italia Inspire 8M (K122254)

5.1 Device Description

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

The gas exchanger part of the Paragon Maxi 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 Paragon Maxi 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.

5.2 Indications for Use

Paragon Adult Maxi PMP Oxygenators (Model: XCMOP405PMP)

The Paragon Adult Maxi 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 Paragon Adult Maxi PMP Oxygenator is intended for clinical use for up to 6 hours.

5.3 Technological Characteristics

The Paragon Maxi has been compared with a predicate device 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),
- Similar base materials,
- Similar packaging materials and configurations,
- Same methods of sterilisation.

The Paragon Maxi is a single use disposable product, supplied sterile, sterilised by ethylene oxide, non-toxic and non-pyrogenic. The shelf life of the Paragon

Maxi has 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),

The following performance characteristics were evaluated for the Paragon Maxi:

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.
Coating Characterization	Non-comparative	Acceptance criteria met by the devices.
Oxygen Transfer Rates	Comparative	No statistically significant difference in the O_2 transfer rates of the Paragon Maxi oxygenator and the predicate.
Carbon Dioxide Transfer Rates	Comparative	No statistically significant difference in the CO_2 transfer rates of the Paragon Maxi oxygenator and the predicate.
Blood Side Pressure Drop	Comparative	The Paragon Maxi has a lower 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 Paragon Maxi 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 Paragon Maxi oxygenator and the predicate.

5.5 Non-Clinical Test Results

The biological safety of the Paragon Maxi has 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 the device.

The Paragon Maxi 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 Paragon Adult Maxi PMP oxygenator is substantially equivalent to the identified predicate device.