October 23, 2020

Abiomed Inc.
% Ken Ryder
Senior Director Global Regulatory Affairs
1500 John Ave Suite 190
Halethorpe, Maryland 21227

Re: K200109
Trade/Device Name: OXY-1 System
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ, KFM, DWA, DWF
Dated: September 21, 2020
Received: September 22, 2020

Dear Ken Ryder:

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,

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)*
K200109

Device Name
OXY-1 System

Indications for Use *(Describe)*
The OXY-1 System is intended to be used for extracorporeal circulation. The OXY-1 System pumps, oxygenates and removes carbon dioxide from blood during cardiopulmonary bypass up to 6 hours in duration

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

I. SUBMITTER

Abiomed, Inc.
22 Cherry Hill Dr.
Danvers, MA 01923
Phone: 978-646-1707

Contact Person: J. Kenneth Ryder
Date Prepared: October 21, 2020

II. DEVICE

Name of Device: OXY-1 System
Common or Usual Name: OXY-1 System
Classification Name: Cardiopulmonary bypass oxygenator
Regulatory Class: II
Product Code: DTZ – Oxygenator, Cardiopulmonary Bypass
KFM – Pump, Blood, Cardiopulmonary Bypass, Non-Roller Type
DWA – Control, Pump Speed, Cardiopulmonary Bypass
DWF – Catheter, Cannula and Tubing, Vascular, Cardiopulmonary Bypass

III. PREDICATE DEVICE(S)

Medtronic Affinity NT (Model 511) Oxygenator (K191029)
Maquet, Rotaflow Pump (K991864)
Maquet, Rotaflow Console (K991864)
Maquet, HLM Tubing Set with Bioline coating (K080592)

IV. DEVICE DESCRIPTION

The Breethe® OXY-1 System provides extracorporeal circulation for full or partial cardiopulmonary bypass support for up to six hours. The OXY-1 System includes; a disposable pump and oxygenator, a pump driver, blood tubing, and a console for powering and controlling the pump and managing gas flow. These components are designed to operate together to reduce the overall equipment footprint at the bedside.

V. INDICATION FOR USE

The OXY-1 System is indicated for:

OXY-1 System	The OXY-1 System is intended to be used for extracorporeal circulation. The OXY-1 System pumps, oxygenates and removes carbon dioxide from blood during cardiopulmonary bypass up to 6 hours in duration.

The identified predicates are indicated for the following:

Medtronic - Affinity NT 511 (K191029)	The AFFINITY® NT Hollow Fiber Oxygenator with Plasma Resistant Fiber is intended to be used in an extracorporeal perfusion circuit to oxygenate and remove carbon dioxide from the blood and to cool or warm the blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.
Maquet - Rotaflow Pump – RF 32 (K991864)	The Rotaflow centrifugal pump system is intended for use in an extracorporeal perfusion circuit to pump blood during short duration cardiopulmonary bypass procedures lasting 6 hours or less.
Maquet - Rotaflow Console (K991864)	The Rotaflow centrifugal pump system is intended for use in an extracorporeal perfusion circuit to pump blood during short duration cardiopulmonary bypass procedures lasting 6 hours or less.
Maquet - HLM Tubing Set with Bioline coating (K080592)	The HLM Tubing Sets with Bioline Coating are designed to be used in extracorporeal circulation during cardiopulmonary bypass procedures lasting six hours or less.

The subject device and the identified predicates have the same intended use for extracorporeal circulation during full or partial cardiopulmonary bypass. The Indications for Use for the OXY-1 System is substantially equivalent to the predicate devices. Differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicates.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Oxygenator Technological Characteristics / Performance Specifications	**Subject Device** ***Oxy-1 System (PLU Disposable)***	**Predicate Device** ***Medtronic - Affinity NT 511 (K191029)***
Materials		
Membrane	Polymethylpentene	Polypropylene
Housing	Polycarbonate	Polycarbonate
Potting	Urethane	Urethane
Design		
Heat Exchanger	No	Yes
Membrane Type	Hollow Fiber	Hollow Fiber
Effective Membrane Surface Area	2.4 m2	2.5 m2
Gas Pathway	Two Gas Pathways	Single Gas Pathway
Oxygenator Geometry	Cylindrical	Cylindrical
Tubing Connectors	3/8”	3/8”
Priming Volume (Oxygenator Only)	285 ml	215 ml
Sterile	SAL 10^-6	SAL 10^-6
Sterilization method	Ethylene Oxide	Ethylene Oxide
Performance Specifications		
Blood Flow Rate	0.5-5.0 Lpm	0.5 – 7.0 Lpm
Gas Transfer	Tested per “Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions” Dated November 13, 2000	Tested per “Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions” Dated November 13, 2000
Hemolysis	Average NIH of 0.0210 mg/100L	Average NIH of 0.0318 mg/100L
Pressure Drop (at 5 Lpm)	Average of 38 mmHg	Average of 52 mmHg

Centrifugal Pump Technological Characteristics / Performance Specifications	**Subject Device** ***Oxy-1 System (PLU Disposable)***	**Predicate Device** ***Maquet - Rotaflow Pump – RF 32 (K991864)***
Materials		
Housing	Polycarbonate	Polycarbonate
Impeller	Polycarbonate	Polycarbonate
Bearing	Polyethylene, Sapphire	Polyethylene, Sapphire
Design		
Pump Operation	Centrifugal pump	Centrifugal pump
Coupling	Magnetic	Magnetic
Bearing	Single pivot	Single pivot
Priming Volume (Pump Only)	34ml	32ml
Tubing Connectors	3/8”	3/8”
Sterile	SAL 10^-6	SAL 10^-6
Sterilization method	Ethylene Oxide	Ethylene Oxide
Performance Specifications		
Blood Flow Rate	0.5-5.0 Lpm	0.5 – 9.0 Lpm
Hemolysis	Average NIH of 0.0210 mg/100L	Average NIH of 0.0318 mg/100L

Controller & Driver Technological Characteristics / Performance Specifications	**Subject Device** ***Oxy-1 System (Console)***	**Predicate Device** ***Maquet - Rotaflow Console (K991864)***
Design		
Coupling	Magnetic	Magnetic
Energy Source	Battery / Mains	Battery / Mains
Other features		
Sweep Gas Source	Internal / External	External
Sighing Gas Source	Internal / External	External
Software		
Constant RPM Mode	Yes	Yes
Constant Flow Mode	No	Yes
-Display		
--Blood Flow	Yes	Yes
--Pump RPM Settings	Yes	Yes
--Internal Sweep Gas Source Settings	Yes	N/A
--Alarm Limit Settings	Yes	Yes
-Alarms		
--Blood Flow	Yes	Yes
--Bubble	Yes	Yes
--Low Battery	Yes	Yes
--System Failure Alarms	Yes	Yes
Hardware		
-Bubble Sensor	Yes	Yes
-Flow Sensor	Yes	Yes
Emergency Drive Unit	Hand Crank	Hand Crank
Performance Specifications		

Controller & Driver Technological Characteristics / Performance Specifications	**Subject Device** ***Oxy-1 System (Console)***	**Predicate Device** ***Maquet - Rotaflow Console (K991864)***
RPM Range	0-4500 RPM	0-5000 RPM

Blood Tubing Technological Characteristics / Performance Specifications	**Subject Device** ***Oxy-1 System (PLU Disposable)***	**Predicate Device** ***Maquet - HLM Tubing Set with Bioline coating (K080592)***
Materials		
Tubing	Polyvinyl Chloride	Polyvinyl Chloride
Surface Treatment	None	Bioline (albumin and heparin)
Design		
Tubing Connectors	3/8"	3/8"

VII. PERFORMANCE DATA

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility Testing:

Biocompatibility testing of the OXY-1 PLU Disposable was conducted for circulating blood for less than 24 hours.

Electrical safety and electromagnetic compatibility (EMC):

The system complies with the IEC 60601-1 standard for electrical safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing:

The software is classified as "major" level of concern. Testing and documentation for a "major" level of concern are provided in the submission.

Performance Testing:

The following testing was conducted as recommended in "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff" dated November 13, 2000.

- Gas Transfer Testing
- Blood and Gas Path Integrity
- Hemolysis
- Hydraulic Performance
- Volatile Organic Compounds
- Particulates evaluation
- ISO 80601-2-69
- Software V&V
- Reliability
- Shelf Life

No animal studies or clinical studies were required or conducted.

VIII. CONCLUSIONS

The OXY-1 System has the same intended use as the identified predicates, has been demonstrated to be substantially equivalent to the identified predicates through performance testing, and the differences do not raise different questions of safety and effectiveness.