February 23, 2023

Abiomed Inc.
Ken Ryder
Sr. Director, Regulatory Affairs
22 Cherry Hill Drive
Danvers, Massachusetts 01923

Re: K223161
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: January 25, 2023
Received: January 27, 2023

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,

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)*

K223261

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Abiomed OXY-1 System 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations, Part 807.92.

A. Application Information:

Date Prepared:	October 06, 2022
Submitter's Name & Address:	ABIOMED, Inc. 22 Cherry Hill Drive Danvers, MA 01923
Contact Person:	J. Kenneth Ryder Senior Director, Global Regulatory Affairs Ph: 978-646-1707 E-mail: kryder@abiomed.com

B. Device Information:

Trade or Proprietary Name:	OXY-1 System
Common or Usual Name:	OXY-1 System
FDA Classification:	Class II, 21 CFR 870.4350
Regulation Description:	Cardiopulmonary bypass oxygenator
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

C. Predicate Device:

The primary predicate device was the OXY-1 System, which is cleared under K200109.

D. Device Description:

The Abiomed OXY-1 System provides extracorporeal circulation for cardiopulmonary bypass support for up to six hours in duration. The OXY-1 System includes:

- A Disposable pump and oxygenator
- A Pump Driver (blood pump)
- Blood tubing
- A Console for controlling the pump and managing gas flow

These components are designed to operate together, simplify operation, and reduce the overall equipment footprint at the bedside.

E. Indications for Use:

INDICATIONS FOR USE:

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.

F. Technological Characteristics Comparison of Subject and Predicate Devices:

The subject device, the OXY-1 System (Configuration 2) is identical to the predicate device Intended Use/Indications for Use, general system components, sterilization, and mechanism of action. Differences between the subject device and the predicate device were all determined to be minor, have no adverse impact on safety or effectiveness, and raise no different questions of safety or effectiveness compared to the predicate device. The minor differences include the oxygenator effective surface area and the presence of a green indicator light on the pump driver.

Technological Characteristics	***Subject Device*** **OXY-1 System (Configuration 2)**	***Predicate Device*** **OXY-1 System (Configuration 1)**
Oxygenator		
Membrane	Polymethylpentene	Polymethylpentene
Housing	Polycarbonate	Polycarbonate
Potting	Urethane	Urethane
Heat Exchanger	No	No
Membrane Type	Hollow Fiber	Hollow Fiber
Effective Membrane Surface Area	2.3 m^2	2.4 m^2
Gas Pathway	Two Gas Pathways	Two Gas Pathways
Oxygenator Geometry	Cylindrical	Cylindrical
Tubing Connectors	3/8”	3/8”
Priming Volume (Oxygenator Only)	285 ml	285 ml
Sterile	SAL 10^-6	SAL 10^-6
Sterilization method	Ethylene Oxide	Ethylene Oxide
Performance Specifications (Oxygenator)		
Blood Flow Rate	0.5-5.0 Lpm	0.5-5.0 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 0.0210 mg/100L
Pressure Drop (at 5 Lpm)	Average of 38 mmHg	Average of 38 mmHg
Console		

Coupling	Magnetic	Magnetic
Energy Source	Battery / Mains	Battery / Mains
Other Features		
Sweep Gas Source	Internal / External	Internal / External
Sighing Gas Source	Internal / External	Internal / External
Software		
Constant RPM Mode	Yes	Yes
Constant Flow Mode	No	No
User Interface/ Display		
Blood Flow	Yes	Yes
Pump RPM Settings	Yes	Yes
Internal Sweep Gas	Yes	Yes
Alarm Limit Settings	Yes	Yes
Blood Flow	Yes	Yes
Bubble	Yes	Yes
Low Battery	Yes	Yes
System Failure Alarms	Yes	Yes
Bubble Sensor	Yes	Yes
Pump Driver		
LED Indicator Light	Yes	No
Controller & Driver		
Flow Sensor	Yes	Yes
Emergency Drive Unit	Hand Crank	Hand Crank
RPM Range	0-4500 RPM	0-4500 RPM
Blood Tubing		
Tubing	Polyvinyl Chloride	Polyvinyl Chloride