March 16, 2026

Lifemotion Medical Technology Co., Ltd.
% Melissa Dehass
Consultant
MEDIcept, Inc.
200 Homer Ave.
Ashland, Massachusetts 01721

Re: K253838
Trade/Device Name: Lifemotion Disposable Membrane Oxygenator
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: February 13, 2026
Received: February 13, 2026

Dear Melissa Dehass:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Kathleen M. Grunder -S

for 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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253838

Please provide the device trade name(s).

Lifemotion Disposable Membrane Oxygenator

Please provide your Indications for Use below.

The Lifemotion Disposable Membrane Oxygenator is indicated for use in cardiopulmonary bypass surgery requiring the extracorporeal oxygenation of and carbon dioxide removal from human blood. It is designed to operate at a blood flow rate of 0.5 to 7.0 liters per minute for periods of up to six (6.0) hours.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY K253838

I. SUBMITTER

510(k) Holder: Lifemotion Medical Technology Co. Ltd
Bldg. 6, Baoxing Wisdom City, No. 650 Zhoushi Road, Bao'An District
518126 Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Contact Person: Melissa DeHass
Regulatory Consultant
MEDIcept, Inc.
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Date Prepared: November 20, 2025

II. DEVICE

Name of Device: Lifemotion Disposable Membrane Oxygenator
Classification Name: Cardiopulmonary bypass oxygenator
Regulatory Class: Class II
Product Code: DTZ – Oxygenator, Cardiopulmonary Bypass

III. PREDICATE DEVICE

K133261, MEDOS Hilite 7000 & 7000 LT Oxygenator

IV. DEVICE DESCRIPTION

The Lifemotion Disposable Membrane Oxygenator is a single use disposable gas exchange device that enables extracorporeal blood gas exchange of oxygen and carbon dioxide through gas permeable hollow fibers as well as blood temperature control by an integrated heat exchanger. The device is ethylene oxide sterilized and packaged in a blister pack.

V. INTENDED USE/INDICATIONS FOR USE

The Lifemotion Disposable Membrane Oxygenator is indicated for use in cardiopulmonary bypass surgery requiring the extracorporeal oxygenation of and carbon dioxide removal from human blood. It is designed to operate at a blood flow rate of 0.5 to 7.0 liters per minute for periods of up to six (6.0) hours.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

In accordance with the *510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* issued July 28, 2014, the comparison between the predicate and the subject devices is shown to be substantially equivalent by comparing the indications for use, principles of operation, technological characteristics, and performance testing similarities and differences. The technological characteristic differences do not raise different questions of safety and effectiveness than the predicate device.

Table 1. Substantial Equivalence Subject Device Lifemotion Disposable Membrane Oxygenator Compared to the Predicate Device Hilite 7000 & 7000 LT (Oxygenator)

Characteristic	**Subject Device** **Lifemotion Disposable Oxygenator** Lifemotion Medical Technology Co. Ltd	**Predicate Device** **Hilite 7000 & 7000 LT (Oxygenator)** **(K133261)** **MEDOS Inc.**	**Equivalence Comparison**
Regulatory Class	Class II	Class II	**Same**
Regulatory Number	870.4350	870.4350	**Same**
Regulation Name	Cardiopulmonary bypass oxygenator	Cardiopulmonary bypass oxygenator	**Same**
Product Code	DTZ	DTZ	**Same**
Intended Use/ Indications for Use	The Lifemotion Disposable Membrane Oxygenator is indicated for use in cardiopulmonary bypass surgery requiring the extracorporeal oxygenation of and carbon dioxide removal from human blood. It is designed to operate at a blood flow rate of 0.5 to 7.0 liters per minute for periods of up to six (6.0) hours.	The MEDOS Hilite 7000 & 7000 LT Oxygenator is indicated for use in procedures requiring the extracorporeal oxygenation of and carbon dioxide removal from human blood. It is designed to operate at a blood flow rate of 1.0 to 7.0 liters per minute for periods of up to six (6.0) hours.	**Same**
Design			
Heat Exchanger	Yes	Yes	**Same**
Membrane Type	Hollow Fiber	Hollow Fiber	**Same**
Effective Membrane Surface Area	2.0 m^2	1.9 m2	**Similar**
Gas Pathway	Single Gas Pathway	Single Gas Pathway	**Same**
Oxygenator Geometry	Cylindrical	Cylindrical	**Same**
Performance Specifications			

Characteristic	Subject Device **Lifemotion Disposable Oxygenator** Lifemotion Medical Technology Co. Ltd	Predicate Device **Hilite 7000 & 7000 LT (Oxygenator)** **(K133261)** **MEDOS Inc.**	Equivalence Comparison
Blood Flow Rate	0.5 – 7.0 Lpm	1.0 – 7.0 Lpm	**Similar**
Gas Transfer	Tested per "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions" date November 13, 2000	Tested per "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions" date November 13, 2000	**Same**

VII. PERFORMANCE DATA

Non-clinical performance testing was conducted to verify the subject device performance. The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility Testing (per ISO 10993-1:2018):
Biocompatibility testing of the Lifemotion Disposable Membrane Oxygenator was conducted for circulating blood for less than 24 hours.

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
- Blood Cell Damage
- Pressure Drop testing
- Heat Exchanger Performance
- Coating Coverage & Coating Integrity
- Shelf Life

No animal or clinical studies were required.

VIII. CONCLUSIONS

The information provided and summarized in the substantial equivalence tables and performance testing results demonstrate that the Lifemotion Disposable Membrane Oxygenator is as safe and effective as the predicate device and support a determination of substantially equivalent.