FDA 510(k) Premarket Notification

CLEARED

K253838 Lifemotion Disposable Membrane Oxygenator

Mar 16, 2026
105 days to decision

K253838 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k253838/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Dec 1, 2025
Decision date	Mar 16, 2026
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lifemotion Medical Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Giuseppe Tomasini
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**MEDIcept, Inc.**
Contact	Melissa DeHass

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov