

K250821 Horizon AF Plus System (Integrated A.L. One AF Plus OXYGENATOR and Horizon CVR) (US5300)Dec 12, 2025
269 days to decisionK250821 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k250821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 18, 2025
Decision date	Dec 12, 2025
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	A.L. One AF Plus OXYGENATOR (US5204); Horizon CVR (US5073)

APPLICANT

Company	Eurosets S.R.L
Location	Medolla, Modena, IT
Contact	Katia Vescovini
510(k) history	6 submissions · 6 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	Accurate Consultants, Inc.
Contact	Sebastian Feye

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250821/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026