

**K231414 CMO8 Adult PMP Oxygenator with Tubing Pack
(Model: CME40009)**Nov 1, 2023
169 days to decisionK231414 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k231414/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	May 16, 2023
Decision date	Nov 1, 2023
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Chalice Medical , Ltd.
Location	Worksop, GB
Contact	Stephen Horan
510(k) history	3 submissions · 3 cleared · 2020-2023

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