

K241366 QualityFlow O2 Series (QualityFLOW O2)Oct 29, 2024
168 days to decisionK241366 · Product code: **CBP** · Anesthesiology
Source: <https://www.510kdatabase.net/k241366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valve, Non-rebreathing (CBP)
Date received	May 14, 2024
Decision date	Oct 29, 2024
Days to decision	168 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	QualityFlow O2 Series (QualityFLOW O2 MTV)

APPLICANT

Company	Dehas Medical Systems GmbH
Location	Luebeck, DE
Contact	Jens Mittendorf
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Draeger Medical Systems, Inc.
Contact	Jens Mittendorf

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k241366/> 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 14, 2026