FDA 510(k) Premarket Notification

K241366 QualityFlow O2 Series (QualityFLOW O2)

CLEARED

Oct 29, 2024
168 days to decision

K241366 · 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