FDA 510(k) Premarket Notification

K240569 FESL FINK Chamber

CLEARED

Nov 21, 2024
266 days to decision

K240569 · Product code: **CBF** · Anesthesiology
Source: https://www.510kdatabase.net/k240569/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chamber, Hyperbaric (CBF)
Date received	Feb 29, 2024
Decision date	Nov 21, 2024
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	FEDL FINK Chamber; FETL FINK Chamber

APPLICANT

Company	**Fink Engineering Pty, Ltd.**
Location	San Antonio, TX, US
Contact	Eric Fink
510(k) history	2 submissions · 2 cleared · 2003-2024

REGULATORY CONSULTANT

Consulting firm	**Biologics Consulting**
Contact	Christy Foreman

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