FDA 510(k) Premarket Notification

K171899 Revitalair 430F

CLEARED

Nov 22, 2019
879 days to decision

K171899 · Product code: **CBF** · Anesthesiology
Source: https://www.510kdatabase.net/k171899/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chamber, Hyperbaric (CBF)
Date received	Jun 26, 2017
Decision date	Nov 22, 2019
Days to decision	879 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Oxavita Srl**
Location	Buenos Aires, AR
Contact	Eduardo Northing
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Emergo Global Consulting, LLC**
Contact	Diane Sudduth

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