

K200698 Somnera SystemJun 29, 2020
104 days to decisionK200698 · Product code: **QBY** · Anesthesiology
Source: <https://www.510kdatabase.net/k200698/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Positive Airway Pressure System (QBY)
Date received	Mar 17, 2020
Decision date	Jun 29, 2020
Days to decision	104 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fresca Medical, Inc.
Location	San Clemente, CA, US
Contact	Mary Lou Mooney
510(k) history	1 submissions · 1 cleared · 2020-2020

CLINICAL EVIDENCE - NCT03999944

Non-Inferiority Study of the FRESCA Airbox Positive Airway Pressure System

Status	Completed
Enrollment	52 patients (actual)
Study sites	6 sites
Condition studied	Sleep Apnea
Primary purpose	Treatment
Study type	Interventional
Study design	Crossover
Masking	Single blind
Completion date	Jan 7, 2020
Sponsor	FRESCA Medical (Industry)

Primary outcome

Apnea-Hypopnea Index (AHI)

Secondary outcome

Oxygen Desaturation Index (ODI)

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03999944
