

K212905 Sotair DeviceAug 18, 2022
339 days to decisionK212905 · Product code: **BTM** · Anesthesiology
Source: <https://www.510kdatabase.net/k212905/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilator, Emergency, Manual (resuscitator) (BTM)
Date received	Sep 13, 2021
Decision date	Aug 18, 2022
Days to decision	339 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Safe Bvm Corporation
Location	Chesterfield, MO, US
Contact	Haris Shekhani
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Fabrica Consulting, LLC
Contact	Sara Toyloy

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

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