FDA 510(k) Premarket Notification

K213894 DWFritz ASM2000

CLEARED

Mar 14, 2022
90 days to decision

K213894 · Product code: **FXX** · General Hospital
Source: https://www.510kdatabase.net/k213894/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 14, 2021
Decision date	Mar 14, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dwfritz Automation, Inc.**
Location	Wilsonville, OR, US
Contact	Curtis Smith
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**FDA 510k Consultants, LLC**
Contact	John Gillespy

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