FDA 510(k) Premarket Notification

K212302 BAYLAB 3-Ply Surgical Mask (BEACON I)

CLEARED

Dec 7, 2021
137 days to decision

K212302 · Product code: **FXX** · General Hospital
Source: https://www.510kdatabase.net/k212302/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 23, 2021
Decision date	Dec 7, 2021
Days to decision	137 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Baylab USA, LLC**
Location	Dallas, TX, US
Contact	Ashley Park
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Freyr Solutions**
Contact	Vardhini Kirthivas

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