

K212302 BAYLAB 3-Ply Surgical Mask (BEACON I)Dec 7, 2021
137 days to decisionK212302 · 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

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