

K212926 Allure™ Surgical MaskSep 16, 2022
367 days to decisionK212926 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k212926/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 14, 2021
Decision date	Sep 16, 2022
Days to decision	367 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Allure Gift Wraps Private Limited
Location	Vapi, IN
Contact	Mohan Jairam Raisinghani
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Allure Life Sciences, LLC
Contact	Sharad Raisinghani

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

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