

K203565 Surgical 3D MaskOct 19, 2021
316 days to decisionK203565 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203565/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 7, 2020
Decision date	Oct 19, 2021
Days to decision	316 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Inno Lifecare
Location	Port Coquitlam, CA
Contact	Jae Ho Lee
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Licensale, Inc.
Contact	Raymond Kelly

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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