

K202214 IFM Surgical Mask Model SM3Mar 2, 2021
208 days to decisionK202214 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202214/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 6, 2020
Decision date	Mar 2, 2021
Days to decision	208 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Fssc, LLC
Location	Rensselaer, IN, US
Contact	Clayton Geyer
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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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