

K210063 Freudenberg Surgical MaskFeb 5, 2021
25 days to decisionK210063 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210063/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 11, 2021
Decision date	Feb 5, 2021
Days to decision	25 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Freudenberg Performance Materials LP
Location	Durham, NC, US
Contact	Eberhard Link
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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