

K212109 Spin Care Disposable Protective Mask Level 3Nov 14, 2021
131 days to decisionK212109 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k212109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 6, 2021
Decision date	Nov 14, 2021
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spintech, LLC
Location	Statesville, NC, US
Contact	Jim Jean
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Rogers Consulting
Contact	W. Victoria Rogers

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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