

K211520 Amerishield Surgical MaskJun 15, 2021
29 days to decisionK211520 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211520/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 17, 2021
Decision date	Jun 15, 2021
Days to decision	29 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Premiurestore, LLC
Location	Virginia Beach, VA, US
Contact	Brent Dillie
510(k) history	2 submissions · 2 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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