

K211440 ASM-301 Level 3 Surgical MaskJun 2, 2021
23 days to decisionK211440 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211440/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 10, 2021
Decision date	Jun 2, 2021
Days to decision	23 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	American Surgical Mask Company, LLC
Location	Tampa, FL, US
Contact	Matt Brandman
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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