

**K222749 High Fluid-Resistant Surgical and Procedure Mask**Nov 14, 2022  
63 days to decisionK222749 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k222749/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 12, 2022
Decision date	Nov 14, 2022
Days to decision	63 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>America?S Supply Chains</b>
Location	Fort Worth, TX, US
Contact	Paul Park
510(k) history	2 submissions · 2 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Technology Services, LLC</b>
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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