

**K211275 AirMax Procedure Mask**May 25, 2021  
28 days to decisionK211275 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k211275/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 27, 2021
Decision date	May 25, 2021
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Premiurestore, LLC</b>
Location	Virginia Beach, VA, US
Contact	Brent Dillie
510(k) history	2 submissions · 2 cleared · 2021-2021

**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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211275/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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