

**K202595 Premier Guard USA 3 Layer Ear Loop ASTM Level 3 Surgical Face Mask**Jan 21, 2021  
135 days to decisionK202595 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k202595/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 8, 2020
Decision date	Jan 21, 2021
Days to decision	135 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Premier Guard USA, LLC</b>
Location	Jackson, MS, US
Contact	Howard Sherman
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Followell Compliance Consultants, LLC</b>
Contact	Valerie Followell

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202595/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026