

**K210131 ComfortGuard Surgical Isolation Gown**Aug 26, 2021  
219 days to decisionK210131 · Product code: **FYC** · General Hospital  
Source: <https://www.510kdatabase.net/k210131/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Jan 19, 2021
Decision date	Aug 26, 2021
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Gri-Alleset, Inc.</b>
Location	Flowery Branch, GA, US
Contact	Marty D Paugh
510(k) history	4 submissions · 4 cleared · 2021-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sterilization Consulting Services, LLC</b>
Contact	Harry L. Shaffer

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/k210131/> 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 26, 2026