

**K210860 Comfort Guard Mask, level 1, Comfort Guard Mask,  
level 3**Apr 7, 2022  
380 days to decisionK210860 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k210860/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 23, 2021
Decision date	Apr 7, 2022
Days to decision	380 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	Martin Paugh
510(k) history	4 submissions · 4 cleared · 2021-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210860/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026