

**K221559 Disposable Surgical Gown, Level 4**Feb 23, 2023  
268 days to decisionK221559 · Product code: **FYA** · General HospitalSource: <https://www.510kdatabase.net/k221559/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	May 31, 2022
Decision date	Feb 23, 2023
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Disposable Surgical Gown, Level 3

**APPLICANT**

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Company	<b>Stringking</b>
Location	Gardena, CA, US
Contact	Thomas Frasca
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221559/> 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