

**K221819 35g Standard SMMS Surgical Gown**Sep 19, 2022  
88 days to decisionK221819 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k221819/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Jun 23, 2022
Decision date	Sep 19, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	35g Reinforced SMMS Surgical Gown;43g Standard SMMS Surgical Gown;43g Reinforced SMMS Surgical Gown ;50g Standard SMMS Surgical Gown; 50g Reinforced SMMS Surgical Gown;BVB Surgical Gown

**APPLICANT**

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Company	<b>Winner Medical Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Mingni Liu
510(k) history	18 submissions · 18 cleared · 2019-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mid-Link Consulting Co, Ltd.</b>
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221819/> 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