

**K211422 Level 2 Standard Surgical Gown, Level 3 Standard Surgical Gown, Level 3 Reinforced Surgical Gown**Jul 2, 2021  
56 days to decisionK211422 · Product code: FYA · General Hospital  
Source: <https://www.510kdatabase.net/k211422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	May 7, 2021
Decision date	Jul 2, 2021
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Jiangsu Medplus Non-Woven Manufacturer Co., Ltd.</b>
Location	Siyang, CN
Contact	Shuying An
510(k) history	2 submissions · 2 cleared · 2021-2021

**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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211422/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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