

**K172445 RoyalGuard Surgical Gown, i600, Breathable**Dec 8, 2017  
116 days to decisionK172445 · Product code: **FYA** · General Hospital  
Source: <https://www.510kdatabase.net/k172445/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Aug 14, 2017
Decision date	Dec 8, 2017
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gri Medical &amp; Electrical Technology Co., Ltd.</b>
Location	Jiaxing, CN
Contact	Martin D. Paugh
510(k) history	3 submissions · 3 cleared · 2016-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172445/> 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 31, 2026