

**K162442 ComfortGuard Plus Surgical Gown, i500,
ComfortGuard Surgical Gown, i500**Dec 12, 2016
103 days to decisionK162442 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k162442/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Aug 31, 2016
Decision date	Dec 12, 2016
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162442/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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