

K163191 ComfortGuard Surgical Gown, i600, Film ReinforcedFeb 27, 2017
105 days to decisionK163191 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k163191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Nov 14, 2016
Decision date	Feb 27, 2017
Days to decision	105 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

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