

K171535 SURGICAL ISOLATION GOWNFeb 15, 2018
266 days to decisionK171535 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k171535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	May 25, 2017
Decision date	Feb 15, 2018
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Jingzhou Haixin Green Cross Medical Products Co., Ltd.
Location	Wuhan, CN
Contact	Rarda L
510(k) history	2 submissions · 2 cleared · 2018-2022

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