

K192290 50g SMS Standard Surgical Gown, 45g SMS Surgical Gown with Reinforcement, 68g BVB Surgical Gown, 68g BVB Splicing Surgical GownApr 30, 2020
251 days to decisionK192290 · Product code: FYA · General Hospital
Source: <https://www.510kdatabase.net/k192290/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Aug 23, 2019
Decision date	Apr 30, 2020
Days to decision	251 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Xuchang Zhengde Environstar Medical Products Co., Ltd.
Location	Xuchang, CN
Contact	Johnny Johnny
510(k) history	2 submissions · 2 cleared · 2020-2022

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