

K211060 Disposable Surgical Gown Rk-3011COct 28, 2022
567 days to decisionK211060 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k211060/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Apr 9, 2021
Decision date	Oct 28, 2022
Days to decision	567 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xiantao Rhycom Non-Woven Products Co., Ltd.
Location	Xiantao, CN
Contact	Liu Yang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Purevisionai, Inc.
Contact	Bryan Wong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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