

K233183 Surgical Gown (40083)Feb 1, 2024
126 days to decisionK233183 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k233183/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 28, 2023
Decision date	Feb 1, 2024
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ammex-Weida (Hubei) Health and Safety Products Co., Ltd.
Location	Xiantao, CN
Contact	Melody Wang
510(k) history	2 submissions · 2 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Jarvis Wu

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