

K202532 Disposable Surgical GownsAug 21, 2021
354 days to decisionK202532 · Product code: **FYA** · General Hospital
Source: <https://www.510kdatabase.net/k202532/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Surgical (FYA)
Date received	Sep 1, 2020
Decision date	Aug 21, 2021
Days to decision	354 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Anhui Medpurest Medical Technology Co.,Ltd
Location	Anqing, CN
Contact	Long Shushan
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202532/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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