

K211538 Protect X Level 3 Isolation GownNov 17, 2021
183 days to decisionK211538 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k211538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	May 18, 2021
Decision date	Nov 17, 2021
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Azac Group
Location	City Of Industry, CA, US
Contact	Yen Ping Shan
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Qpm Consulting, LLC
Contact	Robert Seiple

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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