

K212504 Isolation Gown AAMI Level 3Nov 7, 2021
90 days to decisionK212504 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k212504/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Aug 9, 2021
Decision date	Nov 7, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Kenpax International Limited
Location	Hong Kong, CN
Contact	Solomon Chen
510(k) history	4 submissions · 4 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Joyce Yang

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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