

K222128 Protective Gown AAMI Level 4Aug 8, 2023
386 days to decisionK222128 · Product code: **QPC** · General Hospital
Source: <https://www.510kdatabase.net/k222128/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Non-sterile, Non-isolation, Intended To Provide Moderate Or High Barrier Protection (QPC)
Date received	Jul 18, 2022
Decision date	Aug 8, 2023
Days to decision	386 days
Third-party review	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

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