

K210414 CoverU Disposable Gown with Tape AAMI Level 4 Isolation Gown CoverU Disposable Gown with Tape - Chemo Gown

Oct 21, 2022
617 days to decision

K210414 · Product code: **FYC** · General Hospital
Source: <https://www.510kdatabase.net/k210414/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gown, Isolation, Surgical (FYC)
Date received	Feb 11, 2021
Decision date	Oct 21, 2022
Days to decision	617 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtecs (Taiwan) Corp.
Location	Taipei City, TW
Contact	William Yang
510(k) history	2 submissions · 2 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Jin Services Co.
Contact	Sandy Liu

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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Device record: <https://www.510kdatabase.net/k210414/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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