

K203376 ASTM Level 1/EN14683 Type IIR 3-Ply disposable Surgical Mask, Model number: FM-1400GMar 2, 2022
470 days to decisionK203376 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k203376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 17, 2020
Decision date	Mar 2, 2022
Days to decision	470 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)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k203376/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026