

K203174 Disposable Medical MaskAug 2, 2021
280 days to decisionK203174 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203174/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 26, 2020
Decision date	Aug 2, 2021
Days to decision	280 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dong Guan Kinyet Metal Products Co., Ltd.
Location	Dongguan City, CN
Contact	Emily Zhang
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Imd Medical & Drug Technology Service Institutions
Contact	Salon Chen

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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