

K220637 3 Ply Medical Grade Single Use Procedural Disposable Face MaskMar 25, 2022
21 days to decisionK220637 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k220637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 4, 2022
Decision date	Mar 25, 2022
Days to decision	21 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kdi Med Supply
Location	Fremont, OH, US
Contact	Yolanda Davis
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220637/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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