

K203012 Surgical MaskApr 11, 2021
192 days to decisionK203012 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203012/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Oct 1, 2020
Decision date	Apr 11, 2021
Days to decision	192 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Customfab, Inc.
Location	Garden Grove, CA, US
Contact	Erentia Gillmer
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	leanRAQA, LLCx
Contact	Laura Nygard

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/k203012/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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