FDA 510(k) Premarket Notification

K203012 Surgical Mask

CLEARED

Apr 11, 2021
192 days to decision

K203012 · 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