

K231618 3 Layer Surgical Mask (134252531)Jul 28, 2023
56 days to decisionK231618 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k231618/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 2, 2023
Decision date	Jul 28, 2023
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Original Mattress Factory, Inc.
Location	Cleveland, OH, US
Contact	Nathan Elseser
510(k) history	1 submissions · 1 cleared · 2023-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231618/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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