

K221534 Surgical Face Masks (Ear Loops And Tie-On)Sep 16, 2022
112 days to decisionK221534 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k221534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 27, 2022
Decision date	Sep 16, 2022
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	San-M Package Co., Ltd.
Location	Shimada-City, JP
Contact	Akihiko Goto
510(k) history	3 submissions · 3 cleared · 2016-2022

REGULATORY CONSULTANT

Consulting firm	Globizz Corporation
Contact	Takahiro Haruyama

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/k221534/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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