

K160269 Surgical Face Masks (Ear loops and Tie-on)Sep 6, 2016
217 days to decisionK160269 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k160269/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Feb 2, 2016
Decision date	Sep 6, 2016
Days to decision	217 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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