

K210698 ECOMA Level 2 Disposable Surgical Mask with Ear LoopsAug 19, 2021
164 days to decisionK210698 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k210698/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 8, 2021
Decision date	Aug 19, 2021
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Xianning Eco Medical Articles Co., Ltd.
Location	Xianning, CN
Contact	Wei Zhou
510(k) history	1 submissions · 1 cleared · 2021-2021

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