

K201629 Medical Face MaskDec 14, 2020
181 days to decisionK201629 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k201629/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 16, 2020
Decision date	Dec 14, 2020
Days to decision	181 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Shengquan New Material Co., Ltd.
Location	Jinan, CN
Contact	Xiumei Zhang
510(k) history	3 submissions · 3 cleared · 2020-2021

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