

K201729 Medical MaskDec 3, 2020
162 days to decisionK201729 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k201729/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 24, 2020
Decision date	Dec 3, 2020
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Zhende Medical Co., Ltd.
Location	Shaoxing, CN
Contact	Chen Ming
510(k) history	2 submissions · 2 cleared · 2020-2021

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