

K182515 Surgical Face MaskMay 27, 2019
257 days to decisionK182515 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k182515/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 12, 2018
Decision date	May 27, 2019
Days to decision	257 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wuhan Dymex Healthcare Co., Ltd.
Location	Wuhan, CN
Contact	Ada Liu
510(k) history	4 submissions · 4 cleared · 2019-2022

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