

K210518 Surgical Face MaskJun 14, 2021
111 days to decisionK210518 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210518/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 23, 2021
Decision date	Jun 14, 2021
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shandong Haidike Medical Products Co., Ltd.
Location	Heze, CN
Contact	Lili Xu
510(k) history	3 submissions · 3 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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