

K211750 Disposable Surgical Face Mask, Disposable Surgical Face Mask (Sterile)Dec 20, 2021
196 days to decisionK211750 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k211750/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 7, 2021
Decision date	Dec 20, 2021
Days to decision	196 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	National Bridge Industrial (S.Z.) Co., Ltd.
Location	Shenzhen, CN
Contact	Yang Haixiong
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shenzhen Joyantech Consulting Co., Ltd.
Contact	Grace Liu

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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