

K203426 Surgical Face Mask (non-sterile)Feb 18, 2021
90 days to decisionK203426 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203426/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 20, 2020
Decision date	Feb 18, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nantong Taiweishi Medical Technology Co., Ltd.
Location	Nantong, CN
Contact	Zhang Xuewen
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Mandy Wu

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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