

K252534 Surgical Face Mask (Ear mount)Mar 3, 2026
203 days to decisionK252534 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k252534/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 12, 2025
Decision date	Mar 3, 2026
Days to decision	203 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Zhejiang Hangkang Medical Equipment Co., Ltd.
Location	Yiwu, CN
Contact	Xiaocan Yan
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	Shanghai SUNGO Management Consulting Co., Ltd.
Contact	Ariel Xiang

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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