

K210433 Surgical Face Mask (Ear loops and Tie-on)Jun 7, 2021
115 days to decisionK210433 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210433/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 12, 2021
Decision date	Jun 7, 2021
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210433/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026