

K203418 Surgical Mask (Procedure Mask) (Models: OH02-01, OH02-01 (Bandage))Sep 17, 2021
302 days to decisionK203418 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k203418/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 19, 2020
Decision date	Sep 17, 2021
Days to decision	302 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ningbo Ouhan Medical Device Co., Ltd.
Location	Yuyao City, CN
Contact	Annie Annie
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Pacific Fortune Management, Inc.
Contact	Rafi Wong

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/k203418/> 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