

K201545 Surgical Face MaskFeb 12, 2021
248 days to decisionK201545 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k201545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Jun 9, 2020
Decision date	Feb 12, 2021
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Amphastar Nanjing Pharmaceuticals, Inc.
Location	Nanjing, CN
Contact	Bob Bao
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201545/> 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 27, 2026