

K210101 American-Made Surgical MaskJan 26, 2022
377 days to decisionK210101 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k210101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Jan 14, 2021
Decision date	Jan 26, 2022
Days to decision	377 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Armbrust, Inc.
Location	Pflugerville, TX, US
Contact	Landon Morales
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210101/> 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