

K212366 Heartland Health Surgical MaskFeb 19, 2022
204 days to decisionK212366 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k212366/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Jul 30, 2021
Decision date	Feb 19, 2022
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Heartland Health Products
Location	Cincinnati, OH, US
Contact	Frank Fischer
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212366/> 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