

**K211066 Sovereign America Surgical Mask, Model Number:
2000SM2, Sovereign America Surgical Mask, Model Number:
2000SM3**Aug 19, 2021
129 days to decisionK211066 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211066/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Apr 12, 2021
Decision date	Aug 19, 2021
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Homtex, Inc.
Location	Cullman, AL, US
Contact	Jeremy Wootten
510(k) history	2 submissions · 2 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211066/> 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