

**K201095 Sovereign America Surgical Face Mask**Mar 19, 2021  
329 days to decisionK201095 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k201095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Apr 24, 2020
Decision date	Mar 19, 2021
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201095/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026