

K202697 United Sewing High Fluid Resistant Disposable Face Mask, United Sewing High Fluid Resistant Surgical Mask, United Sewing High Fluid Resistant Procedure MaskMay 13, 2021
239 days to decisionK202697 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k202697/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Sep 16, 2020
Decision date	May 13, 2021
Days to decision	239 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	United Sewing Automation, Inc.
Location	Mount Airy, NC, US
Contact	Benjamin Webb
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Womble Bond Dickinson, US Llp
Contact	Heather Hatcher

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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