

K211536 Welspun Health Surgical MaskSep 1, 2021
106 days to decisionK211536 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	May 18, 2021
Decision date	Sep 1, 2021
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Welspun India Limited
Location	District:Kutch, IN
Contact	Satyapriya Dash
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Liberty Management Group Limited
Contact	Manoj Zacharias

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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