FDA 510(k) Premarket Notification

K212451 Surgical Mask

CLEARED

Sep 10, 2021
36 days to decision

K212451 · Product code: **FXX** · General Hospital
Source: https://www.510kdatabase.net/k212451/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 5, 2021
Decision date	Sep 10, 2021
Days to decision	36 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Remade USA, LLC**
Location	Los Angeles, CA, US
Contact	David Durst
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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