

K202463 Disposable Surgical MaskSep 18, 2020
22 days to decisionK202463 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 27, 2020
Decision date	Sep 18, 2020
Days to decision	22 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Unisources Group, LLC
Location	Miami, FL, US
Contact	Henry Shen
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Accelerated Device Approval Services
Contact	Rafael Aguila

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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