

K230395 Durio Surgical Face Mask, Models 501 (3-ply, blue) and 545 (4-ply,blue)Jul 17, 2023
153 days to decisionK230395 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k230395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 14, 2023
Decision date	Jul 17, 2023
Days to decision	153 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Durio Ppe Sdn Bhd
Location	Johor Bahru, MY
Contact	Xavier Kong
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Emergo by UL
Contact	Sarah Marie Fitzgerald

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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