

K213347 ADI Medical Surgical Face MaskJan 25, 2022
109 days to decisionK213347 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k213347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Oct 8, 2021
Decision date	Jan 25, 2022
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Asia Dynamics Inc., D/B/A Adi Medical
Location	Waukegan, IL, US
Contact	Jonathan Zhu
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mdi Consultants, Inc.
Contact	Timothy Kania

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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