

K211956 039 Surgical Face MaskNov 23, 2021
152 days to decisionK211956 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211956/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 24, 2021
Decision date	Nov 23, 2021
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Aok Tooling Limited
Location	Shenzhen, CN
Contact	Francis Nithyananthan
510(k) history	3 submissions · 3 cleared · 2020-2022

REGULATORY CONSULTANT

Consulting firm	Aok Tooling Limited % Promedic, LLC
Contact	Paul Dryden

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211956/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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