

**K220876 AOK 95A Medical Mask (20200049)**Jul 27, 2022  
124 days to decisionK220876 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k220876/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Mar 25, 2022
Decision date	Jul 27, 2022
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Aok Tooling Limited C/O Promedic, LLC</b>
Contact	Paul Dryden

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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