

**K210422 INTAI Surgical Mask (non-sterile)**Mar 30, 2022  
412 days to decisionK210422 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k210422/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 11, 2021
Decision date	Mar 30, 2022
Days to decision	412 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Intai Technology Corp.</b>
Location	Taichung, TW
Contact	Dale Chang
510(k) history	2 submissions · 2 cleared · 2013-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210422/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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