

**K203388 Disposable medical mask**Jun 4, 2021  
198 days to decisionK203388 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k203388/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 18, 2020
Decision date	Jun 4, 2021
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Everwin Toys (Dongguan),. Ltd.</b>
Location	Dongguan, CN
Contact	Huang Zibin
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Share Info (Guangzhou) Medical Consultant , Ltd.</b>
Contact	Cassie Lee

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203388/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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