

**K212460 Medical Surgical Mask (Model: ZKM-U01(non-sterilized type 17.5cm×9.5cm))**Nov 5, 2021  
92 days to decisionK212460 · Product code: FXX · General Hospital  
Source: <https://www.510kdatabase.net/k212460/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Aug 5, 2021
Decision date	Nov 5, 2021
Days to decision	92 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Guangzhou Zhengkang Medical Equipment Co.,Ltd</b>
Location	Guangzhou, CN
Contact	Mike Wu
510(k) history	2 submissions · 2 cleared · 2021-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Feiyong Drug &amp; Medical Consulting Technical Service Group</b>
Contact	Tracy Che

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/k212460/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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