

**K214035 LAITEST Medical Face Mask**Sep 13, 2022  
264 days to decisionK214035 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k214035/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 23, 2021
Decision date	Sep 13, 2022
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>R&amp;R Medical Corporation, Ltd.</b>
Location	New Taipei City, TW
Contact	Wilson Chang
510(k) history	2 submissions · 2 cleared · 2022-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Voler Biotech Consulting CO., Ltd.</b>
Contact	Chih Hao Kao

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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