

**K223003 Banded Face Mask**Nov 18, 2022  
50 days to decisionK223003 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k223003/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mask, Surgical (FXX)
Date received	Sep 29, 2022
Decision date	Nov 18, 2022
Days to decision	50 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Hubei Medlink Healthcare Co., Ltd.</b>
Location	Wuhan, CN
Contact	Niki Wang
510(k) history	2 submissions · 2 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>CI 3D Devices, LLC</b>
Contact	Cheng Luo

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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