

**K211165 Medical Face Masks, Model Name:MY020003**Nov 9, 2021  
204 days to decisionK211165 · Product code: **FXX** · General HospitalSource: <https://www.510kdatabase.net/k211165/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 19, 2021
Decision date	Nov 9, 2021
Days to decision	204 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Huizhou Jie Bai Purification Co., Ltd.</b>
Location	Huizhou, CN
Contact	Terrance Huang
510(k) history	1 submissions · 1 cleared · 2021-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211165/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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