

**K201470 Disposable Medical Face Mask**Sep 8, 2020  
97 days to decisionK201470 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k201470/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 3, 2020
Decision date	Sep 8, 2020
Days to decision	97 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Jkh USA, LLC</b>
Location	Diamond Bar, CA, US
Contact	Bill Quanqin Dai
510(k) history	9 submissions · 9 cleared · 2019-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201470/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026