

**K201896 ivi N3003 Surgical face Mask, ivi N6006 Surgical mask**Mar 30, 2021  
265 days to decisionK201896 · Product code: **FXX** · General Hospital  
Source: <https://www.510kdatabase.net/k201896/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 8, 2020
Decision date	Mar 30, 2021
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Iob Medical, Inc.</b>
Location	Gaithersburg, MD, US
Contact	Jiulin Xia
510(k) history	7 submissions · 7 cleared · 2014-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>LSI International, Inc.</b>
Contact	Joe Shia

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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