

K211861 TAIJI Professional Series Level 3 Surgical Face MaskJul 28, 2021
42 days to decisionK211861 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211861/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Jun 16, 2021
Decision date	Jul 28, 2021
Days to decision	42 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Taiji Medical Supplies, Inc.
Location	Lincolnton, NC, US
Contact	Katherine Giannamore
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Global Quality and Regulatory Services
Contact	Abdel B Halim

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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