

K210304 Surgical MaskMay 4, 2021
90 days to decisionK210304 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210304/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Feb 3, 2021
Decision date	May 4, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Jin Pin Electrical Co., Ltd. Zhuhai S.E.Z.
Location	Zhuhai, CN
Contact	Rongfeng Yu
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Eva Li

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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