

K202899 Procedure Mask, Surgical MaskMay 20, 2021
233 days to decisionK202899 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k202899/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Sep 29, 2020
Decision date	May 20, 2021
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kenpax International Limited
Location	Hong Kong, CN
Contact	Solomon Chen
510(k) history	4 submissions · 4 cleared · 2021-2023

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Ivy Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202899/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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