

K221838 Surgical Face Mask (HNFM0103)Aug 17, 2022
55 days to decisionK221838 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k221838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jun 23, 2022
Decision date	Aug 17, 2022
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Hua EN Industrial Co, Ltd.
Location	Shanghai, CN
Contact	Lisa Zhao
510(k) history	2 submissions · 2 cleared · 2022-2022

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](https://accessdata.fda.gov)

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