

K212203 Dong Hai Xiang Surgical MaskApr 7, 2022
267 days to decisionK212203 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k212203/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jul 14, 2021
Decision date	Apr 7, 2022
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Taizhou Donghaixiang Protective Equipment Co., Ltd.
Location	Linhai, CN
Contact	Hong Wei
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Getilapson (Dalian) Biological Technology Co., Ltd.
Contact	Shuai Wang

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

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