

K210218 SURGICAL MASK, Model Name:C015May 7, 2021
100 days to decisionK210218 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k210218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Jan 27, 2021
Decision date	May 7, 2021
Days to decision	100 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qingdao Hainuo Biological Engineering Co., Ltd.
Location	Qingdao, CN
Contact	Raphael Wang
510(k) history	1 submissions · 1 cleared · 2021-2021

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210218/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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