

K203528 KNH Surgical Face MaskNov 16, 2022
714 days to decisionK203528 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Dec 2, 2020
Decision date	Nov 16, 2022
Days to decision	714 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Knh Surgical Face Mask
Location	Tainan, TW
Contact	Robert Y.L. Pan
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Knh Enterprise Co., Ltd.
Contact	Brian Wu

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/k203528/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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