

K203078 CAREWE Surgical Face Mask Models N001-AW, N002-AW, and N003-AWAug 19, 2022
675 days to decisionK203078 · Product code: FXX · General Hospital
Source: <https://www.510kdatabase.net/k203078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Mask, Surgical (FXX)
Date received	Oct 13, 2020
Decision date	Aug 19, 2022
Days to decision	675 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Huizhou Tianchang Industrial Co., Ltd.
Location	Huizhou, CN
Contact	Johnny Chan
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Mhetra, LLC
Contact	Viky Verna

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

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