

K203425 Surgical MaskMar 5, 2021
105 days to decisionK203425 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k203425/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Nov 20, 2020
Decision date	Mar 5, 2021
Days to decision	105 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bdc Dental Corporation , Ltd.
Location	Guangzhou, CN
Contact	Lifang Zhang
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	Regulatory Technology Services, LLC
Contact	Prithul Bom

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/k203425/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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