

K211042 Disposable Procedural Ear-loop Face MaskJul 15, 2021
98 days to decisionK211042 · Product code: **FXX** · General Hospital
Source: <https://www.510kdatabase.net/k211042/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mask, Surgical (FXX)
Date received	Apr 8, 2021
Decision date	Jul 15, 2021
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Changzhou Dsb Medical Co., Ltd.
Location	Changzhou, CN
Contact	Sunny Han
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Sungo Management Consulting Company Limited.
Contact	Mandy Wu

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

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