

K201514 Child Face MaskOct 10, 2021
489 days to decisionK201514 · Product code: **OXZ** · General Hospital
Source: <https://www.510kdatabase.net/k201514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pediatric/child Facemask (OXZ)
Date received	Jun 8, 2020
Decision date	Oct 10, 2021
Days to decision	489 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shandong Shengquan New Material Co., Ltd.
Location	Jinan, CN
Contact	Xiumei Zhang
510(k) history	3 submissions · 3 cleared · 2020-2021

REGULATORY CONSULTANT

Consulting firm	Shanghai Landlink Medical Information Technology Co., Ltd.
Contact	Shelley Li

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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