

K213427 PRIMED Pediatric FacemaskNov 22, 2022
397 days to decisionK213427 · Product code: **OXZ** · General Hospital
Source: <https://www.510kdatabase.net/k213427/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pediatric/child Facemask (OXZ)
Date received	Oct 21, 2021
Decision date	Nov 22, 2022
Days to decision	397 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Primed Medical Products, Inc.
Location	Edmonton, Alberta, CA
Contact	Mitra Fard
510(k) history	8 submissions · 8 cleared · 2008-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213427/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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