

K202831 The iMask Child's Face MaskAug 26, 2021
335 days to decisionK202831 · Product code: **OXZ** · General Hospital
Source: <https://www.510kdatabase.net/k202831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pediatric/child Facemask (OXZ)
Date received	Sep 25, 2020
Decision date	Aug 26, 2021
Days to decision	335 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pac-Dent, Inc.
Location	Brea, CA, US
Contact	Jiahe Li
510(k) history	8 submissions · 8 cleared · 2020-2022

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