

**K210321 Dukal Corporation Level 1 Pediatric Face Mask**Mar 29, 2022  
418 days to decisionK210321 · Product code: **OXZ** · General Hospital  
Source: <https://www.510kdatabase.net/k210321/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pediatric/child Facemask (OXZ)
Date received	Feb 4, 2021
Decision date	Mar 29, 2022
Days to decision	418 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dukal Corporation</b>
Location	Hauppauge, NY, US
Contact	Megan Quevedo
510(k) history	7 submissions · 7 cleared · 2007-2022

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