

**K041718 KELES FACEMASK**Oct 15, 2004  
113 days to decisionK041718 · Product code: **DZB** · Dental  
Source: <https://www.510kdatabase.net/k041718/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Headgear, Extraoral, Orthodontic (DZB)
Date received	Jun 24, 2004
Decision date	Oct 15, 2004
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Great Lakes Orthodontics, Ltd.</b>
Location	Mchenry, IL, US
Contact	DAVE GRAVER
510(k) history	13 submissions · 13 cleared · 1983-2018

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