

K232011 CleoJul 7, 2023
1 days to decisionK232011 · Product code: **NJM** · Dental
Source: <https://www.510kdatabase.net/k232011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Jul 6, 2023
Decision date	Jul 7, 2023
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	American Orthodontics
Location	Sheboygan, WI, US
Contact	Laura Richmond
510(k) history	44 submissions · 44 cleared · 1989-2023

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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