

**K220689 Vatech Clismile**May 6, 2022  
58 days to decisionK220689 · Product code: **NJM** · Dental  
Source: <https://www.510kdatabase.net/k220689/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Mar 9, 2022
Decision date	May 6, 2022
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Rayence Co., Ltd.</b>
Location	Houston, TX, US
Contact	Kevin Kim
510(k) history	38 submissions · 38 cleared · 2011-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mtechgroup</b>
Contact	Dave Kim

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

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