

**K131197 EDGEWISE CERAMIC BRACKETS, ROTH CERAMIC BRACKETS**Aug 27, 2013  
123 days to decisionK131197 · Product code: **NJM** · Dental  
Source: <https://www.510kdatabase.net/k131197/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Apr 26, 2013
Decision date	Aug 27, 2013
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dental Morelli</b>
Location	Aventura, FL, US
Contact	TARA CONRAD
510(k) history	2 submissions · 2 cleared · 2013-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131197/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 7, 2026