

**K160615 ORTHODONTIC CERAMIC BRACKETS 1.1**Aug 26, 2016  
176 days to decisionK160615 · Product code: **NJM** · Dental  
Source: <https://www.510kdatabase.net/k160615/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Mar 3, 2016
Decision date	Aug 26, 2016
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tomy, Inc.</b>
Location	Bradenton, FL, US
Contact	JINICHI WATANABE
510(k) history	4 submissions · 4 cleared · 2012-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160615/> 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 19, 2026