

K060837 IN-OVATION CApr 10, 2006
13 days to decisionK060837 · Product code: **NJM** · Dental
Source: <https://www.510kdatabase.net/k060837/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bracket, Ceramic, Orthodontic (NJM)
Date received	Mar 28, 2006
Decision date	Apr 10, 2006
Days to decision	13 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply International
Location	York, PA, US
Contact	HELEN LEWIS
510(k) history	23 submissions · 23 cleared · 2001-2012

Dentsply International is an American dental equipment manufacturer and consumables producer headquartered in York, US. The company designs and manufactures laboratory and specialty products for dental applications, serving markets in over 120 countries. Dentsply International has received FDA 510(k) clearances from total submissions, with all submissions focused on dental devices. The company's regulatory clearance activity spans from 2001 to 2012, establishing a historical record in the dental device sector. No submissions were denied. The company's cleared device portf...
