

**K093221 PRE-CEMENTED ORTHODONTIC BRACKET SYSTEM
EXTENSION II**

Oct 30, 2009
17 days to decision

K093221 · Product code: **DYH** · Dental
Source: <https://www.510kdatabase.net/k093221/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	Oct 13, 2009
Decision date	Oct 30, 2009
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply Intl., Inc.
Location	York, PA, US
Contact	HELEN LEWIS
510(k) history	12 submissions · 12 cleared · 2005-2014

510k Database - www.510kdatabase.net
 Device record: <https://www.510kdatabase.net/k093221/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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