

**K081291 PRE-CEMENTED ORTHODONTIC BRACKET SYSTEM
EXTENSION**May 22, 2008
15 days to decisionK081291 · Product code: **DYH** · Dental
Source: <https://www.510kdatabase.net/k081291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Adhesive, Bracket And Tooth Conditioner, Resin (DYH)
Date received	May 7, 2008
Decision date	May 22, 2008
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply Interntional
Location	York, PA, US
Contact	HELEN LEWIS
510(k) history	13 submissions · 13 cleared · 2007-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081291/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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