

K041335 PTM SYSTEMJun 16, 2004
29 days to decisionK041335 · Product code: **EIH** · Dental
Source: <https://www.510kdatabase.net/k041335/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powder, Porcelain (EIH)
Date received	May 18, 2004
Decision date	Jun 16, 2004
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply International
Location	York, PA, US
Contact	P JEFFERY LEHN
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...
