

K031615 SLED CURING LIGHT SYSTEMJul 21, 2003
59 days to decisionK031615 · Product code: **EBZ** · Dental
Source: <https://www.510kdatabase.net/k031615/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activator, Ultraviolet, For Polymerization (EBZ)
Date received	May 23, 2003
Decision date	Jul 21, 2003
Days to decision	59 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...

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Device record: <https://www.510kdatabase.net/k031615/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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