

K032319 CERA R PLUS ALLOYSep 30, 2003
64 days to decisionK032319 · Product code: **EJT** · DentalSource: <https://www.510kdatabase.net/k032319/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Alloy, Gold-based Noble Metal (EJT)
Date received	Jul 28, 2003
Decision date	Sep 30, 2003
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply International
Location	York, PA, US
Contact	P. JFFERY 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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