

**K030111 DIAMONDCOAT ULTRASONIC INSERTS**Feb 7, 2003  
25 days to decisionK030111 · Product code: **ELC** · DentalSource: <https://www.510kdatabase.net/k030111/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Scaler, Ultrasonic (ELC)
Date received	Jan 13, 2003
Decision date	Feb 7, 2003
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dentsply International</b>
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/k030111/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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