

**K011009 WHITE MTA MATERIAL**May 2, 2001  
28 days to decisionK011009 · Product code: **KIF** · DentalSource: <https://www.510kdatabase.net/k011009/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Root Canal Filling (KIF)
Date received	Apr 4, 2001
Decision date	May 2, 2001
Days to decision	28 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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