

K052097 CERAM X UNIVERSAL MANO-CERAMIC RESTORATIVEAug 12, 2005
9 days to decisionK052097 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k052097/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 3, 2005
Decision date	Aug 12, 2005
Days to decision	9 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply International
Location	York, PA, US
Contact	HELEN LEWIS
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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