

K061580 ECLIPSE WAX REMOVERJul 28, 2006
51 days to decisionK061580 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k061580/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Jun 7, 2006
Decision date	Jul 28, 2006
Days to decision	51 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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k061580/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026