

K061264 TEMPFX ESTHETIC PROVISIONAL SYSTEMMay 23, 2006
18 days to decisionK061264 · Product code: **EBG** · Dental
Source: <https://www.510kdatabase.net/k061264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	May 5, 2006
Decision date	May 23, 2006
Days to decision	18 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsply International, Inc.
Location	York, PA, US
Contact	HELEN LEWIS
510(k) history	36 submissions · 36 cleared · 2006-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k061264/> 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 2, 2026