

K063228 SURFACE COATDec 8, 2006
44 days to decisionK063228 · Product code: **EBD** · Dental
Source: <https://www.510kdatabase.net/k063228/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coating, Filling Material, Resin (EBD)
Date received	Oct 25, 2006
Decision date	Dec 8, 2006
Days to decision	44 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kuraray America, Inc.
Location	New York, NY, US
Contact	KOJI NISHIDA
510(k) history	11 submissions · 11 cleared · 1997-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k063228/> 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 16, 2026