

K062409 K-ETCHANT GELNov 8, 2006
83 days to decisionK062409 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k062409/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 17, 2006
Decision date	Nov 8, 2006
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kuraray Medical, Inc.
Location	New York, NY, US
Contact	KOJI NISHIDA
510(k) history	42 submissions · 42 cleared · 2001-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k062409/> 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 15, 2026