

**K012794 PRIME-DENT CHEMICAL CURE PIT & FISSURE
SEALANT**Nov 5, 2001
76 days to decisionK012794 · Product code: **EBF** · Dental
Source: <https://www.510kdatabase.net/k012794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Aug 21, 2001
Decision date	Nov 5, 2001
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Prime Dental Manufacturing, Inc.
Location	Chicago, IL, US
Contact	ROLANDO MARASIGAN
510(k) history	9 submissions · 9 cleared · 2000-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012794/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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