

**K012761 PRIME-DENT VISIBLE LIGHT CURE PIT & FISSURE SEALANT**

Nov 1, 2001  
76 days to decision

K012761 · Product code: **EBC** · Dental  
Source: <https://www.510kdatabase.net/k012761/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sealant, Pit And Fissure, And Conditioner (EBC)
Date received	Aug 17, 2001
Decision date	Nov 1, 2001
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k012761/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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