

**K101814 DIRECT CROWN NATURAL 1**Sep 27, 2010  
90 days to decisionK101814 · Product code: **EBG** · Dental  
Source: <https://www.510kdatabase.net/k101814/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Crown And Bridge, Temporary, Resin (EBG)
Date received	Jun 29, 2010
Decision date	Sep 27, 2010
Days to decision	90 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Candulor USA, Inc.</b>
Location	Los Angeles, CA, US
Contact	DONNA MARIE HARTNETT
510(k) history	2 submissions · 2 cleared · 2010-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101814/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026