

**K122852 PHYSIOSTAR NFC**Dec 6, 2012  
79 days to decisionK122852 · Product code: **ELM** · Dental  
Source: <https://www.510kdatabase.net/k122852/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Denture, Plastic, Teeth (ELM)
Date received	Sep 18, 2012
Decision date	Dec 6, 2012
Days to decision	79 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/k122852/> 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