

**K122427 CS ORTHODONTIC IMAGING SOFTWARE CS OMS  
IMAGING SOFTWARE**Sep 12, 2012  
34 days to decisionK122427 · Product code: LLZ · Radiology  
Source: <https://www.510kdatabase.net/k122427/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 9, 2012
Decision date	Sep 12, 2012
Days to decision	34 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carestream Dental, LLC</b>
Location	Atlanta, GA, US
Contact	DANIEL HOEFER
510(k) history	1 submissions · 1 cleared · 2012-2012

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122427/>. 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 May 17, 2026