

**K112321 CS 1200**Nov 10, 2011  
90 days to decisionK112321 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k112321/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Aug 12, 2011
Decision date	Nov 10, 2011
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carestream Health, Inc.</b>
Location	Rochester, NY, US
Contact	DANIEL HOEFER
Website	<a href="http://www.carestream.com/default.aspx?LangType=1033">http://www.carestream.com/default.aspx?LangType=1033</a>
510(k) history	48 submissions · 48 cleared · 2008-2025

Carestream Health, Inc. is a worldwide provider of medical imaging systems and X-ray imaging solutions. The company operates with a manufacturing facility in Rochester, US and maintains a global service and support network across multiple markets. Carestream has received FDA 510(k) clearances from total submissions since 2008. The company specializes in Radiology devices, which represent 94% of its regulatory submissions. The latest clearance was granted in 2025, demonstrating continued active development and market engagement. Recent cleared devices include digital radio...

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