

**K092917 STERN'S S250 NORDAM**Jun 24, 2010  
275 days to decisionK092917 · Product code: **EIA** · DentalSource: <https://www.510kdatabase.net/k092917/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Unit, Operative Dental (EIA)
Date received	Sep 22, 2009
Decision date	Jun 24, 2010
Days to decision	275 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Cefla S.C.</b>
Location	Imola (Bo), IT
Contact	BERTHOIN CLAUDE
Website	<a href="https://www.cefla.com">https://www.cefla.com</a>
510(k) history	21 submissions · 21 cleared · 2008-2026

Cefla S.C. is a diversified industrial group based in Imola, Italy. The company operates through multiple business units, including a dedicated Medical Equipment division that develops dental and diagnostic imaging devices. Cefla has maintained a strong FDA 510(k) regulatory record since 2008. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. Its cleared devices span radiology and dental categories, including cone beam computed tomography (CBCT) systems, dental micromotors, and apex locators. The latest clearance was grante...

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