

**K130834 R7**Oct 8, 2013  
196 days to decisionK130834 · Product code: **ELC** · Dental  
Source: <https://www.510kdatabase.net/k130834/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Scaler, Ultrasonic (ELC)
Date received	Mar 26, 2013
Decision date	Oct 8, 2013
Days to decision	196 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Cefla S.C.</b>
Location	Imola (Bo), IT
Contact	Claude Berthoin
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...

---