FDA 510(k) Premarket Notification

K133412 S200, S300

CLEARED

Jan 8, 2015
427 days to decision

K133412 · Product code: **EIA** · Dental
Source: https://www.510kdatabase.net/k133412/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Operative Dental (EIA)
Date received	Nov 7, 2013
Decision date	Jan 8, 2015
Days to decision	427 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Cefla S.C.**
Location	Imola (Bo), IT
Contact	BERTHOIN CLAUDE
Website	https://www.cefla.com
510(k) history	20 submissions · 20 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...