

K231990 Apex LocatorFeb 13, 2024
223 days to decisionK231990 · Product code: **LQY** · Dental
Source: <https://www.510kdatabase.net/k231990/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Locator, Root Apex (LQY)
Date received	Jul 5, 2023
Decision date	Feb 13, 2024
Days to decision	223 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cefla S.C.
Location	Imola (Bo), IT
Contact	Daidone Simona
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...