FDA 510(k) Premarket Notification

K123381 HYPERION X9

CLEARED

May 10, 2013
190 days to decision

K123381 · Product code: **OAS** · Radiology
Source: https://www.510kdatabase.net/k123381/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Nov 1, 2012
Decision date	May 10, 2013
Days to decision	190 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...