

K161900 HYPERION X5Dec 9, 2016
151 days to decisionK161900 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k161900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Jul 11, 2016
Decision date	Dec 9, 2016
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cefla S.C.
Location	Imola (Bo), IT
Contact	SILVIA SANSAVINI
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...
