

K223794 hyperion X9 pro, NewTom GiANO HR, X-RADiUS TRiO PLUSJan 17, 2023
29 days to decisionK223794 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k223794/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Dec 19, 2022
Decision date	Jan 17, 2023
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Cefla S.C.
Location	Imola (Bo), IT
Contact	Lorenzo Bortolotti
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...