

K190496 hyperion X9 pro, NewTom GiANO HR, X-RADiUS TRiO PLUSApr 24, 2019
55 days to decisionK190496 · Product code: **OAS** · Radiology
Source: <https://www.510kdatabase.net/k190496/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Feb 28, 2019
Decision date	Apr 24, 2019
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cefla S.C.
Location	Imola (Bo), IT
Contact	Elena Arcangeli
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...