

**K200688 hyperion X5, NewTom GO, X-RADiUS COMPACT**Apr 9, 2020  
24 days to decisionK200688 · Product code: **OAS** · Radiology  
Source: <https://www.510kdatabase.net/k200688/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	X-ray, Tomography, Computed, Dental (OAS)
Date received	Mar 16, 2020
Decision date	Apr 9, 2020
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cefla S.C.</b>
Location	Imola (Bo), IT
Contact	Lorenzo Bortolotti
Website	<a href="https://www.cefla.com">https://www.cefla.com</a>
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...

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