

K113497 HYPERIONJan 17, 2012
53 days to decisionK113497 · Product code: **MUH** · Radiology
Source: <https://www.510kdatabase.net/k113497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Nov 25, 2011
Decision date	Jan 17, 2012
Days to decision	53 days
Third-party review	Yes
Summary / Statement	Statement

APPLICANT

Company	Cefla S.C. Cefla Dental Group
Location	Imola, IT
Contact	MARISA TESTA
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113497/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026