

**K161131 FONA Pan/Ceph**Nov 3, 2016  
196 days to decisionK161131 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k161131/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, X-ray, Extraoral Source, Digital (MUH)
Date received	Apr 21, 2016
Decision date	Nov 3, 2016
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fona S.R.L</b>
Location	Assago, IT
Contact	ELISA GUSBERTI
510(k) history	4 submissions · 4 cleared · 2016-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161131/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026