

**K120975 CS 8100 CS 8100 ACCESS**Jun 22, 2012  
81 days to decisionK120975 · Product code: **MUH** · Radiology  
Source: <https://www.510kdatabase.net/k120975/>**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 2, 2012
Decision date	Jun 22, 2012
Days to decision	81 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Trophy</b>
Location	Marne La Vallee Cedex 2, FR
Contact	MARIE-PIERRE LABAT-CAMY
510(k) history	15 submissions · 15 cleared · 2008-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k120975/> 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 June 18, 2026