

**K122289 IMAGE-COM 5.0**Oct 24, 2012  
86 days to decisionK122289 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k122289/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 30, 2012
Decision date	Oct 24, 2012
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tomtec Imaging Systems GmbH</b>
Location	Unterschleissheim, DE
Contact	BERNHARD MUMM
510(k) history	21 submissions · 21 cleared · 1999-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122289/> 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 27, 2026