

**K090461 IMAGE-ARENA 4.0 AND IA APPLICATIONS 2D  
CARDIAC PERFORMANCE ANALYSIS 1.0**May 22, 2009  
88 days to decisionK090461 · Product code: LLZ · Radiology  
Source: <https://www.510kdatabase.net/k090461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 23, 2009
Decision date	May 22, 2009
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tomtec Imaging Systems GmbH</b>
Location	Unterschleissheim, DE
Contact	INGE SCHEIDT
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/k090461/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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