

**K132544 TOMTEC-ARENA 1.0, TOMTEC-ARENA 3D ECHO,
CARDIO-ARENA**Nov 25, 2013
104 days to decisionK132544 · Product code: LLZ · Radiology
Source: <https://www.510kdatabase.net/k132544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 13, 2013
Decision date	Nov 25, 2013
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tomtec Imaging Systems GmbH
Location	Unterschleissheim, DE
Contact	CHRISTINE KLEIN
510(k) history	21 submissions · 21 cleared · 1999-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132544/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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