

K213544 TOMTEC-ARENAJan 6, 2022
59 days to decisionK213544 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k213544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Nov 8, 2021
Decision date	Jan 6, 2022
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213544/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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