

K201632 TOMTEC-ARENAAug 14, 2020
59 days to decisionK201632 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k201632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 16, 2020
Decision date	Aug 14, 2020
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

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