

K211542 PRIMO SJul 9, 2021
51 days to decisionK211542 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k211542/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Solid State X-ray Imager (flat Panel/digital Imager) (MQB)
Date received	May 19, 2021
Decision date	Jul 9, 2021
Days to decision	51 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	A.T.S. Applicazione Tecnologie Speciali S.R.L.
Location	Torre De? Roveri, IT
Contact	Livia Pillitteri
510(k) history	4 submissions · 4 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	Kamm & Associates
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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