

K212376 Caas QardiaMay 16, 2022
290 days to decisionK212376 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k212376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 30, 2021
Decision date	May 16, 2022
Days to decision	290 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Pie Medical Imaging BV
Location	Maastricht, NL
Contact	Annemiek Bouts
510(k) history	23 submissions · 23 cleared · 2001-2025

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