

K162376 CAAS MR 4D FlowDec 8, 2016
106 days to decisionK162376 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k162376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 24, 2016
Decision date	Dec 8, 2016
Days to decision	106 days
Third-party review	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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