

K191544 Synapse 3D Blood Flow AnalysisOct 18, 2019
129 days to decisionK191544 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k191544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 11, 2019
Decision date	Oct 18, 2019
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Corporation
Location	Ashigara Kami-Gun, JP
Contact	Randy Vader
510(k) history	62 submissions · 62 cleared · 2018-2026

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