

K162287 Synapse 3D Perfusion AnalysisApr 6, 2017
234 days to decisionK162287 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k162287/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Aug 15, 2016
Decision date	Apr 6, 2017
Days to decision	234 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Medical Systems U.S.A, Inc.
Location	Stamford, CT, US
Contact	Jyh-Shyan Lin
510(k) history	39 submissions · 39 cleared · 2005-2018

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