

K203103 Synapse 3D, Synapse 3D Base Tools v6.1Feb 9, 2021
118 days to decisionK203103 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k203103/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Oct 14, 2020
Decision date	Feb 9, 2021
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	Fujifilm Medical Systems U.S.A, Inc.
Contact	Jeffrey Wan

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

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