FDA 510(k) Premarket Notification

K203103 Synapse 3D, Synapse 3D Base Tools v6.1

CLEARED

Feb 9, 2021
118 days to decision

K203103 · 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