

K110186 SYNAPSE 3D LIVER ANALYSISApr 7, 2011
76 days to decisionK110186 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k110186/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jan 21, 2011
Decision date	Apr 7, 2011
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujifilm Medical System U.S.A., Inc.
Location	Stamford, CT, US
Contact	KIMERLY A SHARP
510(k) history	71 submissions · 71 cleared · 1988-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110186/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 16, 2026