FDA 510(k) Premarket Notification

K110186 SYNAPSE 3D LIVER ANALYSIS

CLEARED

Apr 7, 2011
76 days to decision

K110186 · 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