

K132188 MAMMOGRAPHY VIEWER SMV658

Oct 25, 2013
102 days to decision

K132188 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k132188/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 15, 2013
Decision date	Oct 25, 2013
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k132188/> 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