

K181460 OnePacs SystemOct 11, 2018
129 days to decisionK181460 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k181460/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jun 4, 2018
Decision date	Oct 11, 2018
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Onepacs, LLC
Location	Palo Alto, CA, US
Contact	Justin Falk
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181460/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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