

K161828 kneeEOSOct 3, 2016
90 days to decisionK161828 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k161828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 5, 2016
Decision date	Oct 3, 2016
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Onefit Medical
Location	Besançon, FR
Contact	Julien Simon
510(k) history	5 submissions · 5 cleared · 2014-2018

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