

K181318 ONIS-PACSAug 13, 2018
87 days to decisionK181318 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k181318/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	May 18, 2018
Decision date	Aug 13, 2018
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Digitalcore Co., Ltd.
Location	Tokyo, JP
Contact	Lemoigne Cedric
510(k) history	1 submissions · 1 cleared · 2018-2018

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