

K192531 QyScore SoftwareDec 13, 2019
88 days to decisionK192531 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k192531/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 16, 2019
Decision date	Dec 13, 2019
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Qynapse
Location	Paris, FR
Contact	Olivier Courreges
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Daniel & Daniel Consulting, LLC
Contact	Michael Daniel

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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