FDA 510(k) Premarket Notification

K192531 QyScore Software

CLEARED

Dec 13, 2019
88 days to decision

K192531 · 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