

K200889 iMac 27 & PL 4.0Jun 2, 2020
60 days to decisionK200889 · Product code: **PGY** · Radiology
Source: <https://www.510kdatabase.net/k200889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Display, Diagnostic Radiology (PGY)
Date received	Apr 3, 2020
Decision date	Jun 2, 2020
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Quantum-Spectra, LLC
Location	Wilmington, DE, US
Contact	Marc Leppla
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Quantum Spectra, LLC
Contact	Marc Leppla

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200889/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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