FDA 510(k) Premarket Notification

K202718 Qmenta Care Platform Family

CLEARED

Jun 16, 2021
272 days to decision

K202718 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k202718/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 17, 2020
Decision date	Jun 16, 2021
Days to decision	272 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Mint Labs, Inc., D/B/A. Qmenta**
Location	Boston, MA, US
Contact	Paulo Rodrigues
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Qmenta Imaging S.L.**
Contact	Paulo Rodrigues

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k202718/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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