FDA 510(k) Premarket Notification

K211222 qER-Quant

CLEARED

Jul 30, 2021
98 days to decision

K211222 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k211222/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Apr 23, 2021
Decision date	Jul 30, 2021
Days to decision	98 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Qure.Ai Technologies**
Location	Mumbai, IN
Contact	Pooja Rao
510(k) history	9 submissions · 9 cleared · 2020-2026

REGULATORY CONSULTANT

Consulting firm	**Qure.ai**
Contact	Pooja Rao

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