FDA 510(k) Premarket Notification

K243250 SubtleHD (1.x)

CLEARED

Feb 12, 2025
120 days to decision

K243250 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k243250/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Oct 15, 2024
Decision date	Feb 12, 2025
Days to decision	120 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Subtle Medical, Inc.**
Location	Menlo Park, CA, US
Contact	Ronny Elor
510(k) history	9 submissions · 9 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	**Enzyme Corporation**
Contact	Jared Seehafer

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