FDA 510(k) Premarket Notification

K241329 SubtleSYNTH (1.x)

CLEARED

Jul 11, 2024
62 days to decision

K241329 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k241329/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	May 10, 2024
Decision date	Jul 11, 2024
Days to decision	62 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