FDA 510(k) Premarket Notification

K240290 AiMIFY (1.x)

CLEARED

Aug 21, 2024
202 days to decision

K240290 · Product code: **LLZ** · Radiology
Source: https://www.510kdatabase.net/k240290/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Feb 1, 2024
Decision date	Aug 21, 2024
Days to decision	202 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
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