

K240290 AiMIFY (1.x)Aug 21, 2024
202 days to decisionK240290 · 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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240290/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026