

**K243250 SubtleHD (1.x)**Feb 12, 2025  
120 days to decisionK243250 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k243250/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Enzyme Corporation</b>
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.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243250/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026