

**K254120 SubtleHD-CT (1.x)**May 15, 2026  
147 days to decisionK254120 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k254120/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Dec 19, 2025
Decision date	May 15, 2026
Days to decision	147 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	Alese Devin
510(k) history	11 submissions · 11 cleared · 2018-2026

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