

K254013 SubtleHD-PET (1.x)May 14, 2026
150 days to decisionK254013 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k254013/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Dec 15, 2025
Decision date	May 14, 2026
Days to decision	150 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	Alese Devin
510(k) history	11 submissions · 11 cleared · 2018-2026

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