

K242205 SpectoMed (v1.0)Jan 14, 2025
172 days to decisionK242205 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k242205/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 26, 2024
Decision date	Jan 14, 2025
Days to decision	172 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Specto Medical
Location	Basel, CH
Contact	Charly Leprince
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Charly Leprince

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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