FDA 510(k) Premarket Notification

K242205 SpectoMed (v1.0)

CLEARED

Jan 14, 2025
172 days to decision

K242205 · 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