

K251109 SMARTDentMay 21, 2025
40 days to decisionK251109 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k251109/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Apr 11, 2025
Decision date	May 21, 2025
Days to decision	40 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ray Co., Ltd.
Location	Beverly Hills, CA, US
Contact	Soo Ji Huh
510(k) history	24 submissions · 24 cleared · 2013-2026

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	Dave Yungvirt

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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