FDA 510(k) Premarket Notification

K251109 SMARTDent

CLEARED

May 21, 2025
40 days to decision

K251109 · 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