FDA 510(k) Premarket Notification

K252708 Relu Cloud

CLEARED

Apr 10, 2026
226 days to decision

K252708 · Product code: **QIH** · Dental
Source: https://www.510kdatabase.net/k252708/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Aug 27, 2025
Decision date	Apr 10, 2026
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Relu BV**
Location	Leuven, BE
Contact	Holger Willems
510(k) history	2 submissions · 2 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	**Prime Path Medtech**
Contact	Breanne Butler

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