

K250947 VistaSoft 4.0 and VisionX 4.0Aug 27, 2025
152 days to decisionK250947 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k250947/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Mar 28, 2025
Decision date	Aug 27, 2025
Days to decision	152 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Durr Dental SE
Location	Bietigheim-Bissingen, DE
Contact	Oliver Lange
510(k) history	9 submissions · 9 cleared · 2018-2025

REGULATORY CONSULTANT

Consulting firm	Kamm & Associates
Contact	Daniel Kamm

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

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