FDA 510(k) Premarket Notification

K252091 Surgical Reality Viewer

CLEARED

Jan 29, 2026
210 days to decision

K252091 · Product code: **QIH** · Radiology
Source: https://www.510kdatabase.net/k252091/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Jul 3, 2025
Decision date	Jan 29, 2026
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medicalvr B.V.**
Location	Nieuw-Vennep, NL
Contact	Chris Hordijk
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Medqair Services B.V.**
Contact	Leon Doorn

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