

**K252091 Surgical Reality Viewer**Jan 29, 2026  
210 days to decisionK252091 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k252091/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| 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**

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

**REGULATORY CONSULTANT**

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|-----------------|------------------------------|
| Consulting firm | <b>Medqair Services B.V.</b> |
| Contact         | Leon Doorn                   |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k252091/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026