

K243769 QFR (3.0)

Apr 4, 2025
119 days to decision

K243769 · Product code: **QHA** · Radiology
Source: <https://www.510kdatabase.net/k243769/>

SUBMISSION DETAILS

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | X-ray Angiographic Imaging Based Coronary Vascular Simulation Software Device (QHA) |
| Date received | Dec 6, 2024 |
| Decision date | Apr 4, 2025 |
| Days to decision | 119 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Qfr Solutions BV |
| Location | Leiden, NL |
| Contact | Bob Goedhart |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |
