

K221432 CustomizeAug 3, 2022
78 days to decisionK221432 · Product code: **QIH** · Radiology
Source: <https://www.510kdatabase.net/k221432/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Automated Radiological Image Processing Software (QIH) |
| Date received | May 17, 2022 |
| Decision date | Aug 3, 2022 |
| Days to decision | 78 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | 3D-Side S.A. |
| Location | Mont-Saint-Guibert, BE |
| Contact | Laurent Paul |
| 510(k) history | 3 submissions · 3 cleared · 2021-2022 |

REGULATORY CONSULTANT

| | |
|-----------------|---------------------|
| Consulting firm | Orthogrow NV |
| Contact | Mieke Janssen |

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.netDevice record: <https://www.510kdatabase.net/k221432/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026