

K213469 VALORYNov 18, 2021
21 days to decisionK213469 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k213469/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received | Oct 28, 2021 |
| Decision date | Nov 18, 2021 |
| Days to decision | 21 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Agfa N.V. |
| Location | Mortsel, BE |
| Contact | Wim Govaerts |
| 510(k) history | 6 submissions · 6 cleared · 2019-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------|
| Consulting firm | Agfa US Corp. |
| Contact | ShaeAnn Cavanagh |

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213469/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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