

K213646 Focus HD 35 DetectorMar 29, 2022
145 days to decisionK213646 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k213646/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received | Nov 4, 2021 |
| Decision date | Mar 29, 2022 |
| Days to decision | 145 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Iray Technology Taicang , Ltd. |
| Location | Taicang, CN |
| Contact | Junjie Qian |
| 510(k) history | 21 submissions · 21 cleared · 2018-2023 |

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