

**K222886 Mercu 1717V**Oct 20, 2022  
27 days to decisionK222886 · Product code: **MQB** · Radiology  
Source: <https://www.510kdatabase.net/k222886/>**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         | Sep 23, 2022   |
| Decision date         | Oct 20, 2022   |
| Days to decision      | 27 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222886/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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