

K201591 Flat Panel DetectorSep 3, 2020
83 days to decisionK201591 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k201591/>**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 | Jun 12, 2020 |
| Decision date | Sep 3, 2020 |
| Days to decision | 83 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Ka Imaging, Inc. |
| Location | Waterloo, CA |
| Contact | Samuel To |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201591/> 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 June 28, 2026