

K190311 BIOK7600 Flat Panel DetectorMar 13, 2019
29 days to decisionK190311 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k190311/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Solid State X-ray Imager (flat Panel/digital Imager) (MQB) |
| Date received | Feb 12, 2019 |
| Decision date | Mar 13, 2019 |
| Days to decision | 29 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Biokinometrics, Inc. |
| Location | Carroll, IA, US |
| Contact | Steven Kraus |
| 510(k) history | 3 submissions · 3 cleared · 2018-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190311/> 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