

K151014 Aura DR 43C-AG flat panel detectorJul 13, 2015
88 days to decisionK151014 · Product code: **MQB** · Radiology
Source: <https://www.510kdatabase.net/k151014/>**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 | Apr 16, 2015 |
| Decision date | Jul 13, 2015 |
| Days to decision | 88 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Abyzr Co., Ltd. |
| Location | Hwaseong-Si, KR |
| Contact | JOHN LIM |
| 510(k) history | 1 submissions · 1 cleared · 2015-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151014/> 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 May 16, 2026