

K191959 QuantX Breast MRI Biopsy Guidance PluginNov 8, 2019
108 days to decisionK191959 · Product code: **LLZ** · Radiology
Source: <https://www.510kdatabase.net/k191959/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Image Processing, Radiological (LLZ) |
| Date received | Jul 23, 2019 |
| Decision date | Nov 8, 2019 |
| Days to decision | 108 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Qlarity Imaging |
| Location | Chicago, IL, US |
| Contact | Robert Tomek |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

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