

K213628 VBrainDec 16, 2021
29 days to decisionK213628 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k213628/>**SUBMISSION DETAILS**

| | |
|-----------------------|--------------------------------------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Radiological Image Processing Software For Radiation Therapy (QKB) |
| Date received | Nov 17, 2021 |
| Decision date | Dec 16, 2021 |
| Days to decision | 29 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Vysioneer, Inc. |
| Location | Cambridge, MA, US |
| Contact | Vicki Lin |
| 510(k) history | 3 submissions · 3 cleared · 2021-2021 |

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