

K212116 VBrain-OAROct 12, 2021
97 days to decisionK212116 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k212116/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Jul 7, 2021
Decision date	Oct 12, 2021
Days to decision	97 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212116/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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