

K203235 VBrainMar 19, 2021
136 days to decisionK203235 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k203235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Nov 3, 2020
Decision date	Mar 19, 2021
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Vysioneer, Inc.
Location	Cambridge, MA, US
Contact	Jen-Tang Lu
510(k) history	3 submissions · 3 cleared · 2021-2021

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