

K212915 MVision AI SegmentationMay 3, 2022
232 days to decisionK212915 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k212915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Sep 13, 2021
Decision date	May 3, 2022
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	MVision AI
Location	Helsinki, FI
Contact	Kalpana Jha
510(k) history	1 submissions · 1 cleared · 2022-2022

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