

K220264 EFAI RTSuite CT HN-Segmentation SystemApr 28, 2022
87 days to decisionK220264 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k220264/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Jan 31, 2022
Decision date	Apr 28, 2022
Days to decision	87 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ever Fortune.Ai, Co., Ltd.
Location	Taichung City, TW
Contact	Joseph Chang
510(k) history	15 submissions · 15 cleared · 2021-2026

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