

K250780 ARTAssistantDec 5, 2025
266 days to decisionK250780 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k250780/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Image Processing Software For Radiation Therapy (QKB)
Date received	Mar 14, 2025
Decision date	Dec 5, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Manteia Technologies Co., Ltd.
Location	Xiamen, CN
Contact	Chao Fang
510(k) history	6 submissions · 6 cleared · 2023-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250780/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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