

K252190 DeepBT Detector-PlusApr 10, 2026
270 days to decisionK252190 · Product code: **QKB** · Radiology
Source: <https://www.510kdatabase.net/k252190/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radiological Image Processing Software For Radiation Therapy (QKB) |
| Date received | Jul 14, 2025 |
| Decision date | Apr 10, 2026 |
| Days to decision | 270 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Aitewan Biomedical Technology, Inc. |
| Location | Taipei, TW |
| Contact | Wan-Yuo Guo |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k252190/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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