

K260378 RayvolveMay 12, 2026
96 days to decisionK260378 · Product code: **QBS** · Radiology
Source: <https://www.510kdatabase.net/k260378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Fracture (QBS)
Date received	Feb 5, 2026
Decision date	May 12, 2026
Days to decision	96 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	AZmed
Location	Paris, FR
Contact	Shanni Zeitoun
510(k) history	3 submissions · 3 cleared · 2025-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k260378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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