

K261378 Rayvolve AZchest

Aug 28, 2026
123 days to decision

K261378 · Product code: **QBS** · Radiology
Source: <https://www.510kdatabase.net/k261378/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Fracture (QBS)
Date received	Apr 27, 2026
Decision date	Aug 28, 2026
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	AZmed
Location	Paris, FR
Contact	Victor DE POLLI
510(k) history	4 submissions · 4 cleared · 2025-2026