

K220164 RayvolveJun 2, 2022
133 days to decisionK220164 · Product code: **QBS** · Radiology
Source: <https://www.510kdatabase.net/k220164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Fracture (QBS)
Date received	Jan 20, 2022
Decision date	Jun 2, 2022
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Azmed Sas
Location	Laval, FR
Contact	Patricia Massako
510(k) history	2 submissions · 2 cleared · 2022-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220164/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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