

K242171 TechCare TraumaJan 17, 2025
177 days to decisionK242171 · Product code: **QBS** · Radiology
Source: <https://www.510kdatabase.net/k242171/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Fracture (QBS)
Date received	Jul 24, 2024
Decision date	Jan 17, 2025
Days to decision	177 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Milvue
Location	Paris, FR
Contact	Mathieu Quintin
510(k) history	2 submissions · 2 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	John Smith

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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