

K240712 icobrain ariaNov 7, 2024
237 days to decisionK240712 · Product code: **QBS** · Radiology
Source: <https://www.510kdatabase.net/k240712/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radiological Computer Assisted Detection/diagnosis Software For Fracture (QBS)
Date received	Mar 15, 2024
Decision date	Nov 7, 2024
Days to decision	237 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Icometrix NV
Location	Leuven, BE
Contact	Dirk Smeets
510(k) history	4 submissions · 4 cleared · 2018-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240712/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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