

**K212365 BoneView**Mar 1, 2022  
214 days to decisionK212365 · Product code: **QBS** · Radiology  
Source: <https://www.510kdatabase.net/k212365/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Radiological Computer Assisted Detection/diagnosis Software For Fracture (QBS) |
| Date received         | Jul 30, 2021   |
| Decision date         | Mar 1, 2022  |
| Days to decision      | 214 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Gleamer</b>                        |
| Location       | Saint Mand?, FR                       |
| Contact        | Antoine Tournier                      |
| 510(k) history | 2 submissions · 2 cleared · 2022-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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