

K222176 BoneViewMar 2, 2023
223 days to decisionK222176 · Product code: **QBS** · Radiology
Source: <https://www.510kdatabase.net/k222176/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Radiological Computer Assisted Detection/diagnosis Software For Fracture (QBS) |
| Date received | Jul 22, 2022 |
| Decision date | Mar 2, 2023 |
| Days to decision | 223 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k222176/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026