

**K201928 e-Ortho Shoulder Software**Sep 30, 2020  
82 days to decisionK201928 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k201928/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Jul 10, 2020
Decision date	Sep 30, 2020
Days to decision	82 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>FH Industrie</b>
Location	Quimper Finistere, FR
Contact	Oscar Ramirez
510(k) history	9 submissions · 9 cleared · 2020-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201928/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026