

**K202519 OrthoNext Platform System**Oct 27, 2020  
56 days to decisionK202519 · Product code: **LLZ** · Radiology  
Source: <https://www.510kdatabase.net/k202519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Processing, Radiological (LLZ)
Date received	Sep 1, 2020
Decision date	Oct 27, 2020
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthofix Srl</b>
Location	Rockville, MD, US
Contact	Gianluca Ricadona
510(k) history	36 submissions · 36 cleared · 1995-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202519/> 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 14, 2026