

**K242270 OrthoNext Platform System**Dec 19, 2024  
140 days to decisionK242270 · Product code: **QIH** · Radiology  
Source: <https://www.510kdatabase.net/k242270/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Radiological Image Processing Software (QIH)
Date received	Aug 1, 2024
Decision date	Dec 19, 2024
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orthofix Srl</b>
Location	Rockville, MD, US
Contact	Elvira Taccarelli
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/k242270/> 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