

**K212044 TrueLok Evo**Nov 5, 2021  
128 days to decisionK212044 · Product code: **KTT** · Orthopedic  
Source: <https://www.510kdatabase.net/k212044/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Jun 30, 2021
Decision date	Nov 5, 2021
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Wagoner Consulting Llg</b>
Contact	Cheryl Wagoner

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212044/> 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 13, 2026