

**K252625 The Response Ortho Smart Fixator - Hexapod System**Nov 20, 2025  
93 days to decisionK252625 · Product code: **KTT** · Orthopedic  
Source: <https://www.510kdatabase.net/k252625/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Aug 19, 2025
Decision date	Nov 20, 2025
Days to decision	93 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Response Ortho Solutions, LLC</b>
Location	Boynton Beach, FL, US
Contact	Isin Sehmuz
510(k) history	2 submissions · 2 cleared · 2024-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Regulatory Insight, Inc.</b>
Contact	Kevin Walls

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

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