

K241769 Response Ortho Metaphyseal Hinge Fixator SystemSep 18, 2024
90 days to decisionK241769 · Product code: **KTT** · Orthopedic
Source: <https://www.510kdatabase.net/k241769/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Jun 20, 2024
Decision date	Sep 18, 2024
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Regulatory Insight, Inc.
Contact	Kevin Walls

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

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