

**K230078 TRAX® CR Total Knee System**Nov 3, 2023  
297 days to decisionK230078 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k230078/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH)
Date received	Jan 10, 2023
Decision date	Nov 3, 2023
Days to decision	297 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Amplitude</b>
Location	Valence, FR
Contact	Hugo Catois
510(k) history	2 submissions · 2 cleared · 2017-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>The OrthoMedix Group, Inc.</b>
Contact	J.D. Webb

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230078/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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