

**K211471 Balanced Knee System Uni**Dec 16, 2021  
219 days to decisionK211471 · Product code: **HSX** · Orthopedic  
Source: <https://www.510kdatabase.net/k211471/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Knee, Femorotibial, Non-constrained, Cemented, Metal/polymer (HSX)
Date received	May 11, 2021
Decision date	Dec 16, 2021
Days to decision	219 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ortho Development Corporation</b>
Location	Draper, UT, US
Contact	Divya Palan
510(k) history	14 submissions · 14 cleared · 2015-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k211471/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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