

**K212545 FlexitSystem Knee osteotomy system**Feb 11, 2022  
183 days to decisionK212545 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k212545/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 12, 2021
Decision date	Feb 11, 2022
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Neoste</b>
Location	Round Rock, TX, US
Contact	JD Webb
510(k) history	6 submissions · 6 cleared · 2013-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>The OrthoMedix Group, Inc.</b>
Contact	JD 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/k212545/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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