

**K213895 Distal Humerus Plating System**Jan 13, 2022  
30 days to decisionK213895 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k213895/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 14, 2021
Decision date	Jan 13, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Skeletal Dynamics, Inc.</b>
Location	Miami, FL, US
Contact	Alexandra Rodriguez
510(k) history	20 submissions · 20 cleared · 2020-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213895/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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