

**K231188 ALIGN Radial Head System**Sep 28, 2023  
155 days to decisionK231188 · Product code: **KWI** · Orthopedic  
Source: <https://www.510kdatabase.net/k231188/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Apr 26, 2023
Decision date	Sep 28, 2023
Days to decision	155 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 Rojas
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/k231188/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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