

**K092721 ALIGN RADIAL HEAD SYSTEM**Aug 3, 2010  
333 days to decisionK092721 · Product code: **KWI** · Orthopedic  
Source: <https://www.510kdatabase.net/k092721/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Sep 4, 2009
Decision date	Aug 3, 2010
Days to decision	333 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Skeletal Dynamics, LLC</b>
Location	Shelton, CT, US
Contact	JOSEPH AZARY
510(k) history	18 submissions · 18 cleared · 2010-2018

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