

**K112030 SYNTHES RADIAL HEAD PROSTHESIS SYSTEM**Jun 19, 2012  
340 days to decisionK112030 · Product code: **KWI** · Orthopedic  
Source: <https://www.510kdatabase.net/k112030/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Jul 15, 2011
Decision date	Jun 19, 2012
Days to decision	340 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synthes (Usa), LLC</b>
Location	19380, PA, US
Contact	ANGELA F LASSANDRO
510(k) history	7 submissions · 7 cleared · 2010-2018

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