

K132735 AXIA RADIAL HEAD SYSTEMJan 7, 2014
126 days to decisionK132735 · Product code: **KWI** · Orthopedic
Source: <https://www.510kdatabase.net/k132735/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Sep 3, 2013
Decision date	Jan 7, 2014
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Imds (Innovative Medical Device Systems) - Leis ME
Location	Orlando, FL, US
Contact	ANDREW RYNEARSON
510(k) history	1 submissions · 1 cleared · 2014-2014

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