

K002644 RADIAL HEAD IMPLANTNov 20, 2000
88 days to decisionK002644 · Product code: **KWI** · Orthopedic
Source: <https://www.510kdatabase.net/k002644/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Aug 24, 2000
Decision date	Nov 20, 2000
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Avanta Orthopaedics, Inc.
Location	San Diego, CA, US
Contact	LOUISE M FOCHT
510(k) history	18 submissions · 17 cleared · 1997-2003

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