

K000658 ERS RADIAL HEAD REPLACEMENTMay 11, 2000
73 days to decisionK000658 · Product code: **KWI** · Orthopedic
Source: <https://www.510kdatabase.net/k000658/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Feb 28, 2000
Decision date	May 11, 2000
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	DePuy Orthopaedics, Inc.
Location	Warsaw, IN, US
Contact	LYNNETTE WHITAKER
510(k) history	206 submissions · 204 cleared · 1998-2023

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