

K213563 DePuy Synthes Radial Head Replacement SystemMar 18, 2022
129 days to decisionK213563 · Product code: **KWI** · Orthopedic
Source: <https://www.510kdatabase.net/k213563/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Nov 9, 2021
Decision date	Mar 18, 2022
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	DePuy Synthes
Location	Raynham, MA, US
Contact	Quinn McCarthy
510(k) history	19 submissions · 19 cleared · 1979-2024

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