

K183618 Revolution Radial HeadMay 17, 2019
142 days to decisionK183618 · Product code: **KWI** · Orthopedic
Source: <https://www.510kdatabase.net/k183618/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Dec 26, 2018
Decision date	May 17, 2019
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ignite Orthopedics, Inc.
Location	Warsaw, IN, US
Contact	Russ Parrott
510(k) history	1 submissions · 1 cleared · 2019-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183618/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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