

**K233592 BioPoly Radial Head Implant**Mar 13, 2024  
126 days to decisionK233592 · Product code: **KWI** · Orthopedic  
Source: <https://www.510kdatabase.net/k233592/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Elbow, Hemi-, Radial, Polymer (KWI)
Date received	Nov 8, 2023
Decision date	Mar 13, 2024
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>BioPoly, LLC</b>
Location	Fort Wayne, IN, US
Contact	Herb Schwartz
510(k) history	3 submissions · 3 cleared · 2021-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233592/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 14, 2026