

**K203634 BioPoly Great Toe Hemiarthroplasty Implant**Feb 2, 2021  
53 days to decisionK203634 · Product code: **KWD** · Orthopedic  
Source: <https://www.510kdatabase.net/k203634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	Dec 11, 2020
Decision date	Feb 2, 2021
Days to decision	53 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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Mcra, LLC</b>
Contact	Dave McGurl

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203634/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026