

**K222964 BioPoly Lesser Toe Hemiarthroplasty Implant**Nov 22, 2022  
56 days to decisionK222964 · Product code: **KWD** · Orthopedic  
Source: <https://www.510kdatabase.net/k222964/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Toe, Hemi-, Phalangeal (KWD)
Date received	Sep 27, 2022
Decision date	Nov 22, 2022
Days to decision	56 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)

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