

**K121973 BIOPRO HEMI-EDGE TOE SYSTEM**Oct 30, 2012  
117 days to decisionK121973 · Product code: **KWD** · Orthopedic  
Source: <https://www.510kdatabase.net/k121973/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Prosthesis, Toe, Hemi-, Phalangeal (KWD) |
| Date received         | Jul 5, 2012                              |
| Decision date         | Oct 30, 2012                             |
| Days to decision      | 117 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biopro, Inc.</b>                     |
| Location       | Port Huron, MI, US                      |
| Contact        | AL LIPPINCOTT                           |
| 510(k) history | 41 submissions · 35 cleared · 1987-2017 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121973/> 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 16, 2026