

**K994214 GEM KNEE SYSTEM**Jul 19, 2000  
218 days to decisionK994214 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k994214/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received         | Dec 14, 1999   |
| Decision date         | Jul 19, 2000   |
| Days to decision      | 218 days   |
| Third-party review    | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Kinamed, Inc.</b>                    |
| Location       | Los Angeles, CA, US                     |
| Contact        | JOEL SLOMOFF                            |
| 510(k) history | 33 submissions · 29 cleared · 1988-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k994214/> 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 19, 2026