

**K011904 NEXGEN PRIMARY POROUS PATELLA, MODEL 04-21  
1-III-5878-65-ZZ-(STANDARD),04-212-III-5878-61-ZZ-(MICRO)**Jul 19, 2001  
30 days to decisionK011904 · Product code: **JWH** · Orthopedic  
Source: <https://www.510kdatabase.net/k011904/>**SUBMISSION DETAILS**

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|                       |                                                                                           |
|-----------------------|-------------------------------------------------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                                                        |
| Submission type       | Special                                                                                   |
| Device classification | Prosthesis, Knee, Patellofemoral, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received         | Jun 19, 2001                                                                              |
| Decision date         | Jul 19, 2001                                                                              |
| Days to decision      | 30 days                                                                                   |
| Third-party review    | No                                                                                        |
| Summary / Statement   | Summary                                                                                   |

**APPLICANT**

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|----------------|-----------------------------------------|
| Company        | <b>Implex Corp.</b>                     |
| Location       | Allendale, NJ, US                       |
| Contact        | ROBERT A POGGIE                         |
| 510(k) history | 65 submissions · 61 cleared · 1993-2005 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011904/>; 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