

**K031219 MODIFICATION TO ISKD (INTRAMEDULLARY SKELETAL KINETIC DISTRACTOR)**May 28, 2003  
41 days to decisionK031219 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k031219/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Special   |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received         | Apr 17, 2003  |
| Decision date         | May 28, 2003  |
| Days to decision      | 41 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Orthofix, Inc.</b>                   |
| Location       | Mckinney, TX, US                        |
| Contact        | MARY BIGGERS                            |
| 510(k) history | 57 submissions · 57 cleared · 1996-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031219/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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