

**K090764 NOVATION CFS PRESS-FIT AND CEMENTED STEMS**Apr 21, 2009  
29 days to decisionK090764 · Product code: **LWJ** · Orthopedic  
Source: <https://www.510kdatabase.net/k090764/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                 |
| Submission type       | Special  |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/polymer, Uncemented (LWJ) |
| Date received         | Mar 23, 2009   |
| Decision date         | Apr 21, 2009   |
| Days to decision      | 29 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Exactech, Inc.</b>                                     |
| Location       | Gainesville, FL, US                                       |
| Contact        | TARA R PATTERSON  |
| Website        | <a href="https://www.exac.com/">https://www.exac.com/</a> |
| 510(k) history | 186 submissions · 174 cleared · 1986-2026                 |

Exactech, Inc. operates with a manufacturing facility in Gainesville, US. The company does not offer direct sales or distribution in the United States. Product inquiries and safety concerns are handled through designated company contacts. Exactech has submitted FDA 510(k) applications, resulting in cleared devices. The company's regulatory activity spans from 1986 to 2026, demonstrating sustained engagement with FDA clearance processes. Orthopedic devices represent the dominant focus of the company's portfolio, accounting for approximately 99% of submissions. Recent FDA 5...

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