

K935726 EXACTECH POROUS COATED CRUCIATE RETAINED FEMORAL COMPONENTOct 20, 1994
323 days to decisionK935726 · Product code: JWH · Orthopedic
Source: <https://www.510kdatabase.net/k935726/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent - SN |
| Submission type | Traditional |
| Device classification | Prosthesis, Knee, Patellofemorotibial, Semi-constrained, Cemented, Polymer/metal/polymer (JWH) |
| Date received | Dec 1, 1993 |
| Decision date | Oct 20, 1994 |
| Days to decision | 323 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Exactech, Inc. |
| Location | Gainesville, FL, US |
| Contact | TIM SEESE |
| Website | https://www.exac.com/ |
| 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...