

**K895607 POROUS COATED TOTAL HIP PROS. ACETABULAR COMPONENT**Nov 17, 1989  
60 days to decisionK895607 · Product code: **JDL** · Orthopedic  
Source: <https://www.510kdatabase.net/k895607/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Prosthesis, Hip, Semi-constrained (metal Cemented Acetabular Component) (JDL)
Date received	Sep 18, 1989
Decision date	Nov 17, 1989
Days to decision	60 days
Third-party review	No

**APPLICANT**

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Company	<b>Exactech, Inc.</b>
Location	Gainesville, FL, US
Contact	WILLIAM PETTY
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...