FDA 510(k) Premarket Notification

# K122798 INTEGRIP ACETABULAR SHELL, INTEGRIP REVISION ACETABULAR SHELL

**CLEARED**

Oct 11, 2012
29 days to decision

K122798 · Product code: **LPH** · Orthopedic
Source: https://www.510kdatabase.net/k122798/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/polymer, Porous Uncemented (LPH) |
| Date received | Sep 12, 2012 |
| Decision date | Oct 11, 2012 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Exactech, Inc.** |
| Location | Gainesville, FL, US |
| Contact | AMY TAULBEE |
| 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...