FDA 510(k) Premarket Notification

# K130390 COMPREHENSIVE CONVERTIBLE GLENOID

**CLEARED**

Oct 9, 2013
236 days to decision

K130390 · Product code: **PHX** · Orthopedic
Source: https://www.510kdatabase.net/k130390/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Shoulder Prosthesis, Reverse Configuration (PHX) |
| Date received | Feb 15, 2013 |
| Decision date | Oct 9, 2013 |
| Days to decision | 236 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Biomet Manufacturing, Inc.** |
| Location | Warsaw, IN, US |
| Contact | PATRICIA SANDBORN BERES |
| 510(k) history | 32 submissions · 32 cleared · 1999-2013 |