

K091967 MEDACTA BIPOLAR HEADMar 2, 2010
244 days to decisionK091967 · Product code: **KWY** · Orthopedic
Source: <https://www.510kdatabase.net/k091967/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY) |
| Date received | Jul 1, 2009 |
| Decision date | Mar 2, 2010 |
| Days to decision | 244 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Medacta International S.A. |
| Location | Castel San Pietro, CH |
| Contact | NATALIE J KENNEL |
| Website | https://www.medacta.com |
| 510(k) history | 164 submissions · 164 cleared · 2008-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091967/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026