

K983226 OSTEONICS X CEMENTED HIP STEM SERIESDec 4, 1998
80 days to decisionK983226 · Product code: **JDI** · Orthopedic
Source: <https://www.510kdatabase.net/k983226/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Semi-constrained, Metal/polymer, Cemented (JDI) |
| Date received | Sep 15, 1998 |
| Decision date | Dec 4, 1998 |
| Days to decision | 80 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Osteonics Corp. |
| Location | Mchenry, IL, US |
| Contact | MARYBETH NAUGHTON |
| 510(k) history | 178 submissions · 136 cleared · 1980-2000 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983226/> 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 21, 2026