

K934159 IOI COCR UNIPOLAR PROSTHESISJul 21, 1994
328 days to decisionK934159 · Product code: **KWY** · Orthopedic
Source: <https://www.510kdatabase.net/k934159/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Hemi-, Femoral, Metal/polymer, Cemented Or Uncemented (KWY) |
| Date received | Aug 27, 1993 |
| Decision date | Jul 21, 1994 |
| Days to decision | 328 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Intermedics Orthopedics |
| Location | Mchenry, IL, US |
| Contact | JOANN RINGER |
| 510(k) history | 108 submissions · 82 cleared · 1982-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k934159/> 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