FDA 510(k) Premarket Notification

# K822321 IOI 32 TM FEMORAL COMPONENT

**CLEARED**

Aug 20, 1982
17 days to decision

K822321 · Product code: **KWL** · Orthopedic
Source: https://www.510kdatabase.net/k822321/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Hemi-, Femoral, Metal (KWL) |
| Date received | Aug 3, 1982 |
| Decision date | Aug 20, 1982 |
| Days to decision | 17 days |
| Third-party review | No |

## APPLICANT

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