FDA 510(k) Premarket Notification

# K022218 CADENCE CEMENT RESTRICTOR

**CLEARED**

Aug 12, 2002
34 days to decision

K022218 · Product code: **JDK** · Orthopedic
Source: https://www.510kdatabase.net/k022218/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Prosthesis, Hip, Cement Restrictor (JDK) |
| Date received | Jul 9, 2002 |
| Decision date | Aug 12, 2002 |
| Days to decision | 34 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Spinal Concepts, Inc.** |
| Location | Austin, TX, US |
| Contact | DAVID M HOOPER |
| 510(k) history | 33 submissions · 28 cleared · 1997-2005 |