FDA 510(k) Premarket Notification

# K013663 CEMENT RESTRICTOR

**CLEARED**

Dec 5, 2001
29 days to decision

K013663 · Product code: **JDK** · Orthopedic
Source: https://www.510kdatabase.net/k013663/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent - U |
| Submission type | Special |
| Device classification | Prosthesis, Hip, Cement Restrictor (JDK) |
| Date received | Nov 6, 2001 |
| Decision date | Dec 5, 2001 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Medtronic Sofamor Danek, Inc.** |
| Location | Memphis, TN, US |
| Contact | RICHARD W TREHARNE |
| 510(k) history | 99 submissions · 89 cleared · 2000-2025 |