

**K012255 MEDTRONIC SOFAMOR DANEK CEMENT
RESTRICTOR**Aug 1, 2001
14 days to decisionK012255 · Product code: **JDK** · Orthopedic
Source: <https://www.510kdatabase.net/k012255/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent - U |
| Submission type | Special |
| Device classification | Prosthesis, Hip, Cement Restrictor (JDK) |
| Date received | Jul 18, 2001 |
| Decision date | Aug 1, 2001 |
| Days to decision | 14 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 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012255/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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