

**K013663 CEMENT RESTRICTOR**Dec 5, 2001  
29 days to decisionK013663 · Product code: **JDK** · Orthopedic  
Source: <https://www.510kdatabase.net/k013663/>**SUBMISSION DETAILS**

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|-----------------------|--|
| 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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013663/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026