

**K011443 THREADED CEMENT RESTRICTOR (CR) TITANIUM**Aug 3, 2001  
84 days to decisionK011443 · Product code: **JDK** · Orthopedic  
Source: <https://www.510kdatabase.net/k011443/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Prosthesis, Hip, Cement Restrictor (JDK)
Date received	May 11, 2001
Decision date	Aug 3, 2001
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic Sofamor Danek USA, Inc.</b>
Location	Memphis, TN, US
Contact	RICHARD TREHARNE
510(k) history	170 submissions · 159 cleared · 2000-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011443/> 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 17, 2026