

K010528 TITANIUM CEMENT RESTRICTOR MATERIAL PEEKOct 10, 2001
229 days to decisionK010528 · Product code: **JDK** · Orthopedic
Source: <https://www.510kdatabase.net/k010528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Prosthesis, Hip, Cement Restrictor (JDK)
Date received	Feb 23, 2001
Decision date	Oct 10, 2001
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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