FDA 510(k) Premarket Notification

K012255 MEDTRONIC SOFAMOR DANEK CEMENT RESTRICTOR

CLEARED

Aug 1, 2001
14 days to decision

K012255 · Product code: **JDK** · Orthopedic
Source: https://www.510kdatabase.net/k012255/

SUBMISSION DETAILS

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