FDA 510(k) Premarket Notification

K031837 MODIFICATION TO FORTITUDE CEMENT RESTRICTOR

CLEARED

Jul 24, 2003
38 days to decision

K031837 · Product code: **JDK** · Orthopedic
Source: https://www.510kdatabase.net/k031837/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Hip, Cement Restrictor (JDK)
Date received	Jun 16, 2003
Decision date	Jul 24, 2003
Days to decision	38 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spinal Concepts, Inc.**
Location	Austin, TX, US
Contact	LISA PETERSON
510(k) history	33 submissions · 28 cleared · 1997-2005

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k031837/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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