FDA 510(k) Premarket Notification

K033953 OPTIMESH 500E CEMENT RESTRICTOR

CLEARED

Jul 6, 2004
197 days to decision

K033953 · Product code: **JDK** · Orthopedic
Source: https://www.510kdatabase.net/k033953/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Prosthesis, Hip, Cement Restrictor (JDK)
Date received	Dec 22, 2003
Decision date	Jul 6, 2004
Days to decision	197 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Spineology, Inc.**
Location	Stillwater, MN, US
Contact	PAMELA SNYDER
510(k) history	54 submissions · 51 cleared · 1999-2025