FDA 510(k) Premarket Notification

K010922 TRI-FIX SPINAL FIXATION SYSTEM

CLEARED

Jun 6, 2001
71 days to decision

K010922 · Product code: **MNI** · Orthopedic
Source: https://www.510kdatabase.net/k010922/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Mar 27, 2001
Decision date	Jun 6, 2001
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Endius, Inc.**
Location	Plainville, MA, US
Contact	SUSAN FINNERAN
510(k) history	33 submissions · 33 cleared · 1997-2008