FDA 510(k) Premarket Notification

K042772 EBI ARRAY SPINAL FIXATION SYSTEM AND SPINELINK II SPINAL FIXATION DEVICE

CLEARED

Dec 13, 2004
69 days to decision

K042772 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k042772/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 5, 2004
Decision date	Dec 13, 2004
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ebi, L.P.**
Location	Parsippany, NJ, US
Contact	FREDERIC TESTA
510(k) history	95 submissions · 94 cleared · 1997-2010