

**K042772 EBI ARRAY SPINAL FIXATION SYSTEM AND
SPINELINK II SPINAL FIXATION DEVICE**Dec 13, 2004
69 days to decisionK042772 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042772/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 19, 2026