

K021749 EBI DYNAFIX VS OSTEOTOMY SYSTEMAug 12, 2002
76 days to decisionK021749 · Product code: **NDF** · Orthopedic
Source: <https://www.510kdatabase.net/k021749/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone, Non-spinal, Metallic (NDF)
Date received	May 28, 2002
Decision date	Aug 12, 2002
Days to decision	76 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k021749/> 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