

K031354 EBI OMEGA21 SPINAL FIXATION SYSTEMAug 6, 2003
99 days to decisionK031354 · Product code: **MNI** · Orthopedic
Source: <https://www.510kdatabase.net/k031354/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Orthosis, Spinal Pedicle Fixation (MNI)
Date received	Apr 29, 2003
Decision date	Aug 6, 2003
Days to decision	99 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

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