FDA 510(k) Premarket Notification

K014137 MODIFICATION TO EBI OMEGA 21 SYSTEM

CLEARED

Jan 16, 2002
30 days to decision

K014137 · Product code: **MNH** · Orthopedic
Source: https://www.510kdatabase.net/k014137/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Orthosis, Spondylolisthesis Spinal Fixation (MNH)
Date received	Dec 17, 2001
Decision date	Jan 16, 2002
Days to decision	30 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