FDA 510(k) Premarket Notification

K013739 MODIFICATION TO EBI XFIX DFS SYSTEM

CLEARED

Dec 13, 2001
30 days to decision

K013739 · Product code: **LXT** · Orthopedic
Source: https://www.510kdatabase.net/k013739/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component, Metal Composite (LXT)
Date received	Nov 13, 2001
Decision date	Dec 13, 2001
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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k013739/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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