FDA 510(k) Premarket Notification

K022319 EBI XFIX DFS SYSTEM

CLEARED

Aug 12, 2002
26 days to decision

K022319 · Product code: **KTT** · Orthopedic
Source: https://www.510kdatabase.net/k022319/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Nail/blade/plate Combination, Multiple Component (KTT)
Date received	Jul 17, 2002
Decision date	Aug 12, 2002
Days to decision	26 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