FDA 510(k) Premarket Notification

K013553 PRE-LOADED ULTRAFIX RC

CLEARED

Dec 19, 2001
55 days to decision

K013553 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k013553/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Oct 25, 2001
Decision date	Dec 19, 2001
Days to decision	55 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Linvatec Corp.**
Location	Research Triangle Pa, NC, US
Contact	LAURA D SENEFF
510(k) history	93 submissions · 87 cleared · 1992-2009