FDA 510(k) Premarket Notification

K981692 MENISCAL REPAIR DEVICE

CLEARED

Jul 27, 1998
75 days to decision

K981692 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k981692/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	May 13, 1998
Decision date	Jul 27, 1998
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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