FDA 510(k) Premarket Notification

K042778 BIOANCHOR WITH DISPOSABLE DRIVER, PRELOADED WITH ONE #2 HERCULINE SUTURE

CLEARED

Nov 4, 2004
29 days to decision

K042778 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k042778/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Oct 6, 2004
Decision date	Nov 4, 2004
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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