FDA 510(k) Premarket Notification

K013131 BIOSCREW XTRALOK

CLEARED

Jun 11, 2002
265 days to decision

K013131 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k013131/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Sep 19, 2001
Decision date	Jun 11, 2002
Days to decision	265 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