

K990194 BIOBUTTONSep 17, 1999
239 days to decisionK990194 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k990194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jan 21, 1999
Decision date	Sep 17, 1999
Days to decision	239 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k990194/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026