

K915613 BONE SCREW 3.5 MMFeb 13, 1992
59 days to decisionK915613 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k915613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Dec 16, 1991
Decision date	Feb 13, 1992
Days to decision	59 days
Third-party review	No

APPLICANT

Company	Acu Med, Inc.
Location	Beaverton, OR, US
Contact	RANDALL HUEBNER
510(k) history	48 submissions · 39 cleared · 1990-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k915613/>; 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