

K012001 SMARTSCREWJul 18, 2001
21 days to decisionK012001 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k012001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 27, 2001
Decision date	Jul 18, 2001
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionx Implants, Ltd.
Location	Tampere, FI
Contact	TUIJA ANNALA
510(k) history	12 submissions · 12 cleared · 1999-2003

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012001/> 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 20, 2026