

**K013546 MODIFICATION TO: 1.5 BONE FIXATION KIT, MODELS
BXS6114, BXS6214**Nov 21, 2001
28 days to decisionK013546 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k013546/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Oct 24, 2001
Decision date	Nov 21, 2001
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionx Implants, Inc.
Location	Tampere, FI
Contact	TUIJA ANNALA
510(k) history	18 submissions · 18 cleared · 1998-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013546/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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