

**K042295 SMARTSCREW II, MODELS 232010, 232012, 232014,
232016, 232018, 232020**Sep 16, 2004
23 days to decisionK042295 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k042295/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Aug 24, 2004
Decision date	Sep 16, 2004
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Linvatec Biomaterials, Ltd.
Location	Largo, FL, US
Contact	TUIJA ANNALA
510(k) history	5 submissions · 5 cleared · 2003-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k042295/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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