

**K000616 SMARTWEDGE ACL, MODELS 430623, 430628,
430723, 430728, 430823, 430828**Mar 23, 2000
28 days to decisionK000616 · Product code: MAI · Orthopedic
Source: <https://www.510kdatabase.net/k000616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Feb 24, 2000
Decision date	Mar 23, 2000
Days to decision	28 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

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