

**K993074 SMART NAIL MODELS 521516, 521520,521525, 531516,  
531520. 531525**Dec 10, 1999  
87 days to decisionK993074 · Product code: **MAI** · Orthopedic  
Source: <https://www.510kdatabase.net/k993074/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Sep 14, 1999
Decision date	Dec 10, 1999
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k993074/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 20, 2026