FDA 510(k) Premarket Notification

K993073 SMART SCREW ACL MODELS 237020, 237025, 237030, 238020, 238025, 238030, 239020, 239025, 239030

CLEARED

Dec 6, 1999
83 days to decision

K993073 · Product code: **MAI** · Orthopedic
Source: https://www.510kdatabase.net/k993073/

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 6, 1999
Days to decision	83 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