

K001378 BIOCUFF, MODELS 225718, 225728, 225736, 235718, 235728, 235736Jul 28, 2000
88 days to decisionK001378 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k001378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	May 1, 2000
Decision date	Jul 28, 2000
Days to decision	88 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

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