

K013057 BIOCUFF,C, MODELS 236018, 236028, 236036Oct 12, 2001
30 days to decisionK013057 · Product code: **MAI** · Orthopedic
Source: <https://www.510kdatabase.net/k013057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Biodegradable, Soft Tissue (MAI)
Date received	Sep 12, 2001
Decision date	Oct 12, 2001
Days to decision	30 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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