FDA 510(k) Premarket Notification

K003077 SMARTSCREW MODEL 222006...227510

CLEARED

Apr 26, 2001
205 days to decision

K003077 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k003077/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Oct 3, 2000
Decision date	Apr 26, 2001
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Bionx Implants, Ltd.**
Location	Tampere, FI
Contact	GERARD S CARLOZZI
510(k) history	12 submissions · 12 cleared · 1999-2003