FDA 510(k) Premarket Notification

K010847 K'FIX

CLEARED

Jun 19, 2001
90 days to decision

K010847 · Product code: **NDL** · Orthopedic
Source: https://www.510kdatabase.net/k010847/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth, Metallic (NDL)
Date received	Mar 21, 2001
Decision date	Jun 19, 2001
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Avanta Orthopaedics, Inc.**
Location	San Diego, CA, US
Contact	LOUISE M FOCHT
510(k) history	18 submissions · 17 cleared · 1997-2003