FDA 510(k) Premarket Notification

K030500 ORIA ZENITH

CLEARED

Mar 20, 2003
29 days to decision

K030500 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k030500/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 19, 2003
Decision date	Mar 20, 2003
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ortho Tec, LLC**
Location	Pleasant Hill, CA, US
Contact	PATRICK BERTRANOU
510(k) history	22 submissions · 22 cleared · 1999-2004