FDA 510(k) Premarket Notification

K010466 TETHER ACFS

CLEARED

May 16, 2001
89 days to decision

K010466 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k010466/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Feb 16, 2001
Decision date	May 16, 2001
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Theken Surgical,Llc**
Location	Barberton, OH, US
Contact	ROBERT THEKEN
510(k) history	6 submissions · 4 cleared · 1998-2005