FDA 510(k) Premarket Notification

K050965 TRANS1 AXIALIF SYSTEM

CLEARED

Jun 14, 2005
57 days to decision

K050965 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k050965/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Apr 18, 2005
Decision date	Jun 14, 2005
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Trans1 Incorporated**
Location	Wilmington, NC, US
Contact	ROBERT L SHERIDAN
510(k) history	9 submissions · 9 cleared · 2005-2012