FDA 510(k) Premarket Notification

K132310 ASCOT

CLEARED

Dec 23, 2013
151 days to decision

K132310 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k132310/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jul 25, 2013
Decision date	Dec 23, 2013
Days to decision	151 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Backroads Consulting, Inc.**
Location	Chesterland, OH, US
Contact	KAREN E WARDEN, PHD
510(k) history	1 submissions · 1 cleared · 2013-2013