

K132310 ASCOTDec 23, 2013
151 days to decisionK132310 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132310/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 17, 2026