FDA 510(k) Premarket Notification

CLEARED

K100061 CAYMAN SCREWS MODEL K2-12-1000-XX, K2-12-1001-XX

Feb 12, 2010
32 days to decision

K100061 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k100061/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Jan 11, 2010
Decision date	Feb 12, 2010
Days to decision	32 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**K2m, Inc.**
Location	Leesburg, VA, US
Contact	RICHARD W WOODS
510(k) history	100 submissions · 97 cleared · 2007-2026