FDA 510(k) Premarket Notification

K131533 CAYMAN MI PLATE SYSTEM

CLEARED

Nov 9, 2013
168 days to decision

K131533 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k131533/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	May 25, 2013
Decision date	Nov 9, 2013
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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