FDA 510(k) Premarket Notification

K132122 KESTREL POSTERIOR CERVICAL SPINE SYSTEM

CLEARED

Jan 22, 2014
196 days to decision

K132122 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k132122/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Jul 10, 2013
Decision date	Jan 22, 2014
Days to decision	196 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Omni Surgical, LLC Dba Spine360**
Location	Austin, TX, US
Contact	DAVE LAMB
510(k) history	1 submissions · 1 cleared · 2014-2014