FDA 510(k) Premarket Notification

K140734 NEXTGEN ALTIUS OCT SYSTEM

CLEARED

Dec 15, 2014
266 days to decision

K140734 · Product code: **KWP** · Orthopedic
Source: https://www.510kdatabase.net/k140734/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Interlaminal (KWP)
Date received	Mar 24, 2014
Decision date	Dec 15, 2014
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ebi, LLC**
Location	Parsippany, NJ, US
Contact	TED KUHN
510(k) history	4 submissions · 4 cleared · 2011-2014