FDA 510(k) Premarket Notification

K160982 Sphynx™

CLEARED

Dec 22, 2016
259 days to decision

K160982 · Product code: **KWQ** · Orthopedic
Source: https://www.510kdatabase.net/k160982/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Appliance, Fixation, Spinal Intervertebral Body (KWQ)
Date received	Apr 7, 2016
Decision date	Dec 22, 2016
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Eden Spine, LLC**
Location	Apple Valley, MN, US
Contact	Guillaume Viallaneix
510(k) history	2 submissions · 2 cleared · 2012-2016