FDA 510(k) Premarket Notification

K192915 GMA 2.0 Pedicle Screw System

CLEARED

Nov 13, 2019
29 days to decision

K192915 · Product code: **NKB** · Orthopedic
Source: https://www.510kdatabase.net/k192915/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Thoracolumbosacral Pedicle Screw System (NKB)
Date received	Oct 15, 2019
Decision date	Nov 13, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Grafton Medical Alliance**
Location	Burr Ridge, IL, US
Contact	James Henry
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	**Jalex Medical**
Contact	Cassie Sopko

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k192915/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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