FDA 510(k) Premarket Notification

K182943 VERTEX Nitinol Staple System

CLEARED

Apr 4, 2019
163 days to decision

K182943 · Product code: **JDR** · Orthopedic
Source: https://www.510kdatabase.net/k182943/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Fixation, Bone (JDR)
Date received	Oct 23, 2018
Decision date	Apr 4, 2019
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nvision Biomedical Technologies, LLC**
Location	San Antonio, TN, US
Contact	Diana Langham
510(k) history	10 submissions · 10 cleared · 2014-2019

REGULATORY CONSULTANT

Consulting firm	**Watershed Ideas Foundry**
Contact	Jeffrey Brittan

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