

K182943 VERTEX Nitinol Staple SystemApr 4, 2019
163 days to decisionK182943 · 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](https://accessdata.fda.gov)

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