FDA 510(k) Premarket Notification

K192645 Trigon™ Ti Stand-Alone Wedge Fixation System

CLEARED

Dec 23, 2019
90 days to decision

K192645 · Product code: **PLF** · Orthopedic
Source: https://www.510kdatabase.net/k192645/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Wedge (PLF)
Date received	Sep 24, 2019
Decision date	Dec 23, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Nvision Biomedical Technologies, Inc.**
Location	San Antonio, TX, US
Contact	Diana Langham
510(k) history	24 submissions · 24 cleared · 2019-2026

REGULATORY CONSULTANT

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

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