FDA 510(k) Premarket Notification

K220197 Trigon HA Wedge Fixation System

CLEARED

Feb 23, 2022
30 days to decision

K220197 · Product code: **PLF** · Orthopedic
Source: https://www.510kdatabase.net/k220197/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Wedge (PLF)
Date received	Jan 24, 2022
Decision date	Feb 23, 2022
Days to decision	30 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	**Nvision Biomedical Technologies**
Contact	Analaura Villarreal-Berain

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