

**K193414 Trigon HA Stand-Alone Wedge Fixation System**Feb 25, 2020  
78 days to decisionK193414 · Product code: **PLF** · Orthopedic  
Source: <https://www.510kdatabase.net/k193414/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bone Wedge (PLF)
Date received	Dec 9, 2019
Decision date	Feb 25, 2020
Days to decision	78 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Watershed Idea Foundry</b>
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)510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193414/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated June 28, 2026