

**K203445 Trigon HA Stand-Alone Wedge Fixation System**Dec 21, 2020  
28 days to decisionK203445 · Product code: **PLF** · Orthopedic  
Source: <https://www.510kdatabase.net/k203445/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Wedge (PLF)
Date received	Nov 23, 2020
Decision date	Dec 21, 2020
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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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**

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Consulting firm	<b>Nvision Biomedical Technologies</b>
Contact	Analaura Villarreal Berain

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/k203445/> 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