

**K243231 Trigon PEEK HA Wedges**Nov 8, 2024  
30 days to decisionK243231 · Product code: **PLF** · Orthopedic  
Source: <https://www.510kdatabase.net/k243231/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Bone Wedge (PLF)
Date received	Oct 9, 2024
Decision date	Nov 8, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nvision Biomedical Technologies</b>
Location	San Antonio, TX, US
Contact	Natalia Reyes
510(k) history	4 submissions · 4 cleared · 2024-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243231/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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