

K234116 Trigon Trigon HA Stand-Alone Wedge Fixation SystemJan 26, 2024
30 days to decisionK234116 · Product code: **PLF** · Orthopedic
Source: <https://www.510kdatabase.net/k234116/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Bone Wedge (PLF) |
| Date received | Dec 27, 2023 |
| Decision date | Jan 26, 2024 |
| Days to decision | 30 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Nvision Biomedical Technologies |
| Location | San Antonio, TX, US |
| Contact | Analaura Villarreal Berain |
| 510(k) history | 4 submissions · 4 cleared · 2024-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k234116/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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