

K250646 Impact PEEK Union Nail SystemJun 11, 2025
99 days to decisionK250646 · Product code: **HTY** · Orthopedic
Source: <https://www.510kdatabase.net/k250646/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Mar 4, 2025
Decision date	Jun 11, 2025
Days to decision	99 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	Erin Lansdale
510(k) history	4 submissions · 4 cleared · 2024-2025

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