

**K253423 ToeJack MIS Bunion System**Nov 18, 2025  
54 days to decisionK253423 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k253423/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Sep 25, 2025
Decision date	Nov 18, 2025
Days to decision	54 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	Marisa Zack
510(k) history	24 submissions · 24 cleared · 2019-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253423/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026