

K253325 ZipToe™ Hammertoe Fusion SystemDec 29, 2025
90 days to decisionK253325 · Product code: HTY · Orthopedic
Source: <https://www.510kdatabase.net/k253325/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Sep 30, 2025
Decision date	Dec 29, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Toetal Solutions
Location	Malvern, PA, US
Contact	Bill Rhoda
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Danielle Besal

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253325/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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