

**K253749 Affixus® Natural Nail® Proximal Humeral System**Dec 12, 2025  
17 days to decisionK253749 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k253749/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Nov 25, 2025
Decision date	Dec 12, 2025
Days to decision	17 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zimmer Switzerland Manufacturing GmbH</b>
Location	Winterthur, CH
Contact	Melanie Mitrov
510(k) history	4 submissions · 4 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k253749/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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