

K253080 AND Medical Femoral Nail System (PFNA01)Jun 18, 2026
268 days to decisionK253080 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k253080/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Sep 23, 2025
Decision date	Jun 18, 2026
Days to decision	268 days
Third-party review	No
Summary / Statement	Summary
Other names	AND Medical Femoral Nail System (PFNA02)

APPLICANT

Company	Suzhou and Science & Technology Development Corp.
Location	Zhangjiagang, CN
Contact	Limin Zhu
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253080/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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