

K234075 Flow-NailFeb 5, 2024
26 days to decisionK234075 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k234075/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Jan 10, 2024
Decision date	Feb 5, 2024
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Flow-Fx, LLC
Location	Washington, DC, US
Contact	Patrick Sweeney
510(k) history	4 submissions · 4 cleared · 2014-2024

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Hollace Rhodes

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

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