

K221115 Flow-NailMay 13, 2022
28 days to decisionK221115 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k221115/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Rod, Fixation, Intramedullary And Accessories (HSB)
Date received	Apr 15, 2022
Decision date	May 13, 2022
Days to decision	28 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 J. Sweeney
510(k) history	4 submissions · 4 cleared · 2014-2024

REGULATORY CONSULTANT

Consulting firm	Mcra, LLC
Contact	Hollace S. Rhodes

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k221115/> Data sourced from FDA 510(k) public records (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. - Generated May 27, 2026