

K230053 SimpliFix Hip SystemApr 19, 2023
103 days to decisionK230053 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k230053/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jan 6, 2023
Decision date	Apr 19, 2023
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stabiliz Orthopaedics, Inc.
Location	Exton, PA, US
Contact	Douglas Cerynik
510(k) history	2 submissions · 2 cleared · 2023-2026

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/k230053/> 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 25, 2026