

K233567 OsteoCoil™ Nitinol Compression System (Multiple Component PNs)Nov 22, 2024
382 days to decisionK233567 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k233567/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Nov 6, 2023
Decision date	Nov 22, 2024
Days to decision	382 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Flower Orthopedics Corporation Db
Location	Horsham, PA, US
Contact	Christina Rovaldi
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Flower Orthopedics Corporation Db
Contact	Christina Rovaldi

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/k233567/>; 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 14, 2026