

**K201556 Intraosseous Fixation System**Jul 8, 2020  
28 days to decisionK201556 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k201556/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 10, 2020
Decision date	Jul 8, 2020
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Extremity Medical, LLC</b>
Location	Parsippany, NJ, US
Contact	Mary Hoffman
510(k) history	28 submissions · 28 cleared · 2008-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201556/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026