

**K121349 IO FIX, IO FIX PLUS, CARPALFIX, EXTREMITY
MEDICAL SCREW AND WASHER**Jul 18, 2012
75 days to decisionK121349 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k121349/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Screw, Fixation, Bone (HWC) |
| Date received | May 4, 2012 |
| Decision date | Jul 18, 2012 |
| Days to decision | 75 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Extremity Medical, LLC |
| Location | Parsippany, NJ, US |
| Contact | JAMY GANNOE |
| 510(k) history | 28 submissions · 28 cleared · 2008-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121349/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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