

**K111663 TRAUMA INTERNAL FIXATION SYSTEMS**Mar 12, 2012  
272 days to decisionK111663 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k111663/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jun 14, 2011
Decision date	Mar 12, 2012
Days to decision	272 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>DePuy Orthopaedics, Inc.</b>
Location	Warsaw, IN, US
Contact	SUZANA OTANO
510(k) history	206 submissions · 204 cleared · 1998-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k111663/> 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 26, 2026