

**K093900 EDGELOCK**Feb 17, 2010  
61 days to decisionK093900 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k093900/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Dec 18, 2009
Decision date	Feb 17, 2010
Days to decision	61 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Orthohelix Surgical Designs, Inc.</b>
Location	Cleveland, OH, US
Contact	DEREK LEWIS
510(k) history	25 submissions · 25 cleared · 2005-2014

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093900/> 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 17, 2026