

**K082399 PECTUS STRUT**Nov 5, 2009  
442 days to decisionK082399 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k082399/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Aug 20, 2008
Decision date	Nov 5, 2009
Days to decision	442 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Koros USA, Inc.</b>
Location	Moorepark, CA, US
Contact	TIBOR KOROS
510(k) history	4 submissions · 4 cleared · 2007-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082399/> 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 18, 2026