

**K011910 IN-FAST BONE SCREW SYSTEM**Jul 13, 2001  
24 days to decisionK011910 · Product code: **HWC** · Orthopedic  
Source: <https://www.510kdatabase.net/k011910/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Jun 19, 2001
Decision date	Jul 13, 2001
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>American Medical Systems, Inc.</b>
Location	Mchenry, IL, US
Contact	ELSA A LINKE
510(k) history	72 submissions · 72 cleared · 1979-2013

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011910/> 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