

**K020446 MODIFICATION TO STRAIGHT-IN BONE SCREW
FIXATION SYSTEM**Mar 13, 2002
30 days to decisionK020446 · Product code: **HWC** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k020446/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Screw, Fixation, Bone (HWC)
Date received	Feb 11, 2002
Decision date	Mar 13, 2002
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k020446/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026