

K012342 AMS SOFT-TISSUE APPROXIMATION SYSTEMSep 5, 2001
43 days to decisionK012342 · Product code: **FZP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k012342/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clip, Implantable (FZP)
Date received	Jul 24, 2001
Decision date	Sep 5, 2001
Days to decision	43 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/k012342/> 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