

**K010990 AMS SLING FIXATION SYSTEM**Jun 22, 2001  
80 days to decisionK010990 · Product code: **GAW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k010990/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                    |
| Submission type       | Traditional   |
| Device classification | Suture, Nonabsorbable, Synthetic, Polypropylene (GAW) |
| Date received         | Apr 3, 2001   |
| Decision date         | Jun 22, 2001  |
| Days to decision      | 80 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010990/> 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