

**K971332 AMS MAINSTAY UROLOGIC BONE ANCHOR**Jul 9, 1997  
90 days to decisionK971332 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k971332/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Apr 10, 1997
Decision date	Jul 9, 1997
Days to decision	90 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	JOHN M OTTO
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/k971332/> 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