

**K082006 AMS SPECTRA CONCEALABLE PENILE PROSTHESIS**Oct 20, 2008  
97 days to decisionK082006 · Product code: **FAE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k082006/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Prosthesis, Penile (FAE)           |
| Date received         | Jul 15, 2008                       |
| Decision date         | Oct 20, 2008                       |
| Days to decision      | 97 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        | STEPHANIE GEORGE                        |
| 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/k082006/> 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