

**K260271 Strauss Surgical cystoscope, hysteroscope and accessories Instruments**Mar 27, 2026  
58 days to decisionK260271 · Product code: FAJ · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k260271/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | Cystoscope And Accessories, Flexible/rigid (FAJ) |
| Date received         | Jan 28, 2026                                     |
| Decision date         | Mar 27, 2026                                     |
| Days to decision      | 58 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>American Medical Endoscopy, Inc.</b> |
| Location       | Doral, FL, US                           |
| Contact        | Matthew Schwimmer                       |
| 510(k) history | 2 submissions · 2 cleared · 2025-2026   |

**REGULATORY CONSULTANT**

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|-----------------|--------------------|
| Consulting firm | <b>Shaily Shah</b> |
| Contact         | Shaily Shah        |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k260271/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 13, 2026