

**K945889 KARL STORZ PLASTIC SURGERY ACCESSORIES**Mar 22, 1995  
111 days to decisionK945889 · Product code: **GCM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k945889/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Endoscope, Rigid (GCM)             |
| Date received         | Dec 1, 1994                        |
| Decision date         | Mar 22, 1995                       |
| Days to decision      | 111 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>KARL STORZ Endoscopy-America, Inc.</b> |
| Location       | Mchenry, IL, US                           |
| Contact        | MARIKA ANDERSON                           |
| 510(k) history | 361 submissions · 361 cleared · 1980-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k945889/> 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 15, 2026