

**K991264 <GENX> SINGLE LUMEN SIDEPORT NEEDLE**Sep 9, 1999  
149 days to decisionK991264 · Product code: **MQE** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k991264/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | Needle, Assisted Reproduction (MQE) |
| Date received         | Apr 13, 1999                        |
| Decision date         | Sep 9, 1999                         |
| Days to decision      | 149 days                            |
| Third-party review    | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

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|----------------|---|
| Company        | <b>&lt;Genx&gt; Intl., Inc.</b>         |
| Location       | Madison, CT, US                         |
| Contact        | MICHAEL D CECCHI                        |
| 510(k) history | 32 submissions · 32 cleared · 1996-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k991264/> 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 June 14, 2026