

**K042935 GEMINI GXL**Nov 9, 2004  
15 days to decisionK042935 · Product code: **KPS** · Radiology  
Source: <https://www.510kdatabase.net/k042935/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | System, Tomography, Computed, Emission (KPS) |
| Date received         | Oct 25, 2004                                 |
| Decision date         | Nov 9, 2004                                  |
| Days to decision      | 15 days                                      |
| Third-party review    | Yes  |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|--|
| Company        | <b>Philips Medical Systems (Cleveland), Inc.</b> |
| Location       | Mchenry, IL, US                                  |
| Contact        | RAE ANN FARROW                                   |
| 510(k) history | 190 submissions · 190 cleared · 1977-2017        |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042935/> 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 16, 2026