

**K101892 HEINE GAMMA G7**Aug 27, 2010  
51 days to decisionK101892 · Product code: **DXQ** · CardiovascularSource: <https://www.510kdatabase.net/k101892/>**SUBMISSION DETAILS**

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|                       |                                                                                                          |
|-----------------------|----------------------------------------------------------------------------------------------------------|
| Decision              | Substantially Equivalent (Cleared)                                                                       |
| Submission type       | Traditional                                                                                              |
| Device classification | Blood Pressure Cuff (DXQ)                                                                                |
| Date received         | Jul 7, 2010                                                                                              |
| Decision date         | Aug 27, 2010                                                                                             |
| Days to decision      | 51 days                                                                                                  |
| Third-party review    | No                                                                                                       |
| Summary / Statement   | Summary                                                                                                  |
| Other names           | HEINE GAMMA G5, HEINE GAMMA GP, HEINE GAMMA GST, HEINE GAMMA XXL LF MODEL M-000.09.23X, M-000.09.24X, M- |

**APPLICANT**

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|----------------|--------------------------------------------|
| Company        | <b>Heine Optotechnik GmbH &amp; Co. KG</b> |
| Location       | Hamburg, DE                                |
| Contact        | THOMAS WEBER                               |
| 510(k) history | 7 submissions · 7 cleared · 2010-2015      |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101892/> 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 4, 2026