

**K081203 OB TRACEVUE OBSTETRICAL INFORMATION  
MANAGEMENT SYSTEM WITH RELEASE F.00**May 28, 2008  
30 days to decisionK081203 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k081203/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Special                             |
| Device classification | System, Monitoring, Perinatal (HGM) |
| Date received         | Apr 28, 2008                        |
| Decision date         | May 28, 2008                        |
| Days to decision      | 30 days                             |
| Third-party review    | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

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|----------------|--|
| Company        | <b>Philips Medizin Systeme Boeblingen GmbH</b> |
| Location       | B?blingen, DE                                  |
| Contact        | MICHAEL ASMALSKY                               |
| 510(k) history | 48 submissions · 48 cleared · 2004-2026        |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081203/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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