

**K002548 FETAL ASSIST**Mar 6, 2001  
201 days to decisionK002548 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k002548/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | System, Monitoring, Perinatal (HGM) |
| Date received         | Aug 17, 2000                        |
| Decision date         | Mar 6, 2001                         |
| Days to decision      | 201 days                            |
| Third-party review    | No                                  |
| Summary / Statement   | Summary                             |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Huntleigh Diagnostics , Ltd.</b>   |
| Location       | Cardiff Wales, GB                     |
| Contact        | B.J. COLLEYPRIEST                     |
| 510(k) history | 3 submissions · 3 cleared · 2000-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k002548/> 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 29, 2026