

**K861556 MODIFIED FETAL MONITOR MODEL FM-2**Jul 7, 1986  
73 days to decisionK861556 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k861556/>**SUBMISSION DETAILS**

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|                       |                                     |
|-----------------------|-------------------------------------|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Traditional                         |
| Device classification | System, Monitoring, Perinatal (HGM) |
| Date received         | Apr 25, 1986                        |
| Decision date         | Jul 7, 1986                         |
| Days to decision      | 73 days                             |
| Third-party review    | No                                  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Advantage Medical Systems, Inc.</b>  |
| Location       | Mchenry, IL, US                         |
| Contact        | ANTHONY CALDERONI                       |
| 510(k) history | 17 submissions · 16 cleared · 1980-1987 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861556/>; 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 27, 2026