

K150901 Fetal & Maternal Monitor, models F6, F6 Express, F9, F9 ExpressJul 1, 2015
89 days to decisionK150901 · Product code: **HGM** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k150901/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Monitoring, Perinatal (HGM) |
| Date received | Apr 3, 2015 |
| Decision date | Jul 1, 2015 |
| Days to decision | 89 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Edan Instruments, Inc. |
| Location | Shenzhen, CN |
| Contact | Queena Chen |
| Website | https://www.edan.com.cn |
| 510(k) history | 92 submissions · 92 cleared · 2004-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150901/> Data sourced from FDA 510(k) public records (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. - Generated June 4, 2026