FDA 510(k) Premarket Notification

# K150901 Fetal & Maternal Monitor, models F6, F6 Express, F9, F9 Express

**CLEARED**

Jul 1, 2015
89 days to decision

K150901 · 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 |