FDA 510(k) Premarket Notification

# K791035 FETASONDE FETAL ACTIVITY MONITOR

**CLEARED**

Sep 4, 1979
91 days to decision

K791035 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k791035/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Monitoring, Perinatal (HGM) |
| Date received | Jun 5, 1979 |
| Decision date | Sep 4, 1979 |
| Days to decision | 91 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Roche Medical Electronics, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 16 submissions · 16 cleared · 1976-1979 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k791035/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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