FDA 510(k) Premarket Notification

# K903623 MODEL600 UTERINE ACTIVITY MONITOR

**CLEARED**

Nov 7, 1990
90 days to decision

K903623 · Product code: **HFM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k903623/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Uterine Contraction, External (for Use In Clinic) (HFM) |
| Date received | Aug 9, 1990 |
| Decision date | Nov 7, 1990 |
| Days to decision | 90 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Corometrics Medical Systems, Inc.** |
| Location | Wallingford, CT, US |
| Contact | BRIAN R BARRY |
| 510(k) history | 5 submissions · 5 cleared · 1988-1998 |