FDA 510(k) Premarket Notification

# K963711 BABY DOPPLEX (3000)

**CLEARED**

Sep 12, 1997
361 days to decision

K963711 · Product code: **HGM** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k963711/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Monitoring, Perinatal (HGM) |
| Date received | Sep 16, 1996 |
| Decision date | Sep 12, 1997 |
| Days to decision | 361 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Huntleigh Healthcare, Inc.** |
| Location | Eatontown, NJ, US |
| Contact | AUDREY WITKO |
| 510(k) history | 14 submissions · 14 cleared · 1993-2004 |