

K001882 BABY DOPPLEX 4002-TWINS, MODEL BD4002Sep 19, 2000
90 days to decisionK001882 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k001882/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Monitoring, Perinatal (HGM) |
| Date received | Jun 21, 2000 |
| Decision date | Sep 19, 2000 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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