

K010889 BABY DOPPLEX 3000 MK 2 (BD3000)Apr 25, 2001
30 days to decisionK010889 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k010889/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Mar 26, 2001
Decision date	Apr 25, 2001
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Huntleigh Healthcare, Inc.
Location	Eatontown, NJ, US
Contact	B.J. COLLEYPRIEST
510(k) history	14 submissions · 14 cleared · 1993-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010889/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 18, 2026