

**K965008 BIRTHNET II PERINATAL PATIENT DATA
MANAGEMENT SYSTEM**Dec 16, 1997
365 days to decisionK965008 · Product code: **HGM** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k965008/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Dec 16, 1996
Decision date	Dec 16, 1997
Days to decision	365 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Spacelabs Medical, Inc.
Location	Hamden, CT, US
Contact	ANTHONY CALDERONI
510(k) history	35 submissions · 34 cleared · 1993-2012

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