

**K871385 MODEL U-1000 WITH GESTATIONAL AGE  
CALCULATION**May 26, 1987  
49 days to decisionK871385 · Product code: **HGM** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k871385/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Apr 7, 1987
Decision date	May 26, 1987
Days to decision	49 days
Third-party review	No

**APPLICANT**

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Company	<b>Fukuda Denshi USA, Inc.</b>
Location	Mchenry, IL, US
Contact	DONALD ANDRESEN
510(k) history	68 submissions · 68 cleared · 1984-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k871385/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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