

K994008 BIOSYS FETAL MONITOR, MODEL IFM-500Sep 29, 2000
310 days to decisionK994008 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k994008/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Nov 24, 1999
Decision date	Sep 29, 2000
Days to decision	310 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosys Co. , Ltd.
Location	San Leandro, CA, US
Contact	GARY J ALLSEBROOK
510(k) history	1 submissions · 1 cleared · 2000-2000

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