

K043597 FC 700 FETAL MONITORDec 16, 2005
352 days to decisionK043597 · Product code: **HGM** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k043597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Dec 29, 2004
Decision date	Dec 16, 2005
Days to decision	352 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bionet Co., Ltd.
Location	Wonju, Kwangwon-Do, KR
Contact	SUN-YOUNG JEONG
510(k) history	11 submissions · 11 cleared · 2005-2023

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