

K955559 COROMETRICS FETAL MOVEMENT DETECTION KITMar 5, 1996
90 days to decisionK955559 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k955559/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Dec 6, 1995
Decision date	Mar 5, 1996
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ge Medical Systems Information Technologies
Location	Mchenry, IL, US
Contact	MARIA VITUG FOUTS
510(k) history	136 submissions · 132 cleared · 1978-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955559/> 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 26, 2026