

K141194 FM-3000 FETAL MONITORNov 19, 2014
195 days to decisionK141194 · Product code: **HGM** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k141194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	May 8, 2014
Decision date	Nov 19, 2014
Days to decision	195 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Instrumentations, Inc.
Location	Hialeah, FL, US
Contact	JORGE MILLAN
510(k) history	16 submissions · 16 cleared · 2009-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141194/> 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 16, 2026