

K052190 FETAL MONITOR, MODELS BT-300 AND BT-200Oct 4, 2005
54 days to decisionK052190 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k052190/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Aug 11, 2005
Decision date	Oct 4, 2005
Days to decision	54 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Bistos Co., Ltd.
Location	Flintville, TN, US
Contact	CHARLIE MACK
510(k) history	11 submissions · 11 cleared · 2005-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052190/> 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 25, 2026