

**K100885 FETAL MONITOR MODEL: BT-200T**Jun 7, 2010  
69 days to decisionK100885 · Product code: **HGM** · Radiology  
Source: <https://www.510kdatabase.net/k100885/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Mar 30, 2010
Decision date	Jun 7, 2010
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bistos Co., Ltd.</b>
Location	Flintville, TN, US
Contact	YOUNG CHI
510(k) history	11 submissions · 11 cleared · 2005-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100885/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026