

K103545 BT-350May 13, 2011
162 days to decisionK103545 · Product code: **HGM** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k103545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Monitoring, Perinatal (HGM)
Date received	Dec 2, 2010
Decision date	May 13, 2011
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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