

**K251512 Hi bebe super (BT-150B)**Sep 25, 2025  
132 days to decisionK251512 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k251512/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Breast, Powered (HGX)
Date received	May 16, 2025
Decision date	Sep 25, 2025
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bistos Co., Ltd.</b>
Location	Flintville, TN, US
Contact	HYE JEONG KIM
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/k251512/> 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 13, 2026