

K200675 Hi bebe super (Models BT-150S and BT-150L)Feb 10, 2021
331 days to decisionK200675 · Product code: **HGX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k200675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Breast, Powered (HGX)
Date received	Mar 16, 2020
Decision date	Feb 10, 2021
Days to decision	331 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Mtechgroup
Contact	Dave Kim

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200675/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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