

K242031 Béa Applicator (BAP-GB-01)Apr 2, 2025
265 days to decisionK242031 · Product code: **HDR** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k242031/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cap, Cervical (HDR)
Date received	Jul 11, 2024
Decision date	Apr 2, 2025
Days to decision	265 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stepone Fertility Ltd (T/A B?a Fertility)
Location	London, GB
Contact	Tom Littleford
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242031/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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