

K191431 Interlude Rolled Tampons in Plastic ApplicatorOct 7, 2019
131 days to decisionK191431 · Product code: **HEB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k191431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tampon, Menstrual, Unscented (HEB)
Date received	May 29, 2019
Decision date	Oct 7, 2019
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Albaad Fem
Location	Caesarea Ind. Park, IL
Contact	Shlomo Helvits
510(k) history	3 submissions · 3 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	Regulatory Technical Associates
Contact	Robert. J. Staab

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/k191431/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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