

K221356 Wee BellFeb 2, 2023
268 days to decisionK221356 · Product code: **HFX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k221356/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Clamp, Circumcision (HFX)
Date received	May 10, 2022
Decision date	Feb 2, 2023
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Wee Medical
Location	Knoxville, TN, US
Contact	D Preston Smith
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Grace Powers - Powers Regulatory Consulting
Contact	Grace Powers

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/k221356/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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