FDA 510(k) Premarket Notification

# K221356 Wee Bell

**CLEARED**

Feb 2, 2023
268 days to decision

K221356 · Product code: **HFX** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k221356/

## SUBMISSION DETAILS

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|---|---|
| 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