

K231203 Mosie Baby KitNov 29, 2023
216 days to decisionK231203 · Product code: **QYZ** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k231203/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	At Home Intravaginal Insemination System (QYZ)
Date received	Apr 27, 2023
Decision date	Nov 29, 2023
Days to decision	216 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Mosie Baby
Location	Austin, TX, US
Contact	Maureen Brown
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Parexel International
Contact	Julie Engel

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

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