

K232579 Twoplus ApplicatorDec 21, 2023
118 days to decisionK232579 · Product code: **QYZ** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k232579/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	At Home Intravaginal Insemination System (QYZ)
Date received	Aug 25, 2023
Decision date	Dec 21, 2023
Days to decision	118 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Hannah Life Technologies Pte , Ltd.
Location	Singapore, SG
Contact	Prusothman M Sina Raja
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	Matrix Medical Consulting, Inc.
Contact	Alan Donald

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

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