FDA 510(k) Premarket Notification

K222932 INVOcell Intravaginal Culture System

CLEARED

Jun 22, 2023
269 days to decision

K222932 · Product code: **OYO** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k222932/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture, Intravaginal, Assisted Reproduction (OYO)
Date received	Sep 26, 2022
Decision date	Jun 22, 2023
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Invo Bioscience**
Location	Medford, MA, US
Contact	Steve Shum
Website	http://www.invobioscience.com/
510(k) history	2 submissions · 1 cleared · 2015-2023

Invo Bioscience is a fertility technology company focused on Obstetrics & Gynecology devices. The company operates fertility clinics and develops innovative reproductive technologies to expand access to advanced fertility care. The company has received FDA 510(k) clearance from total submissions in the Obstetrics & Gynecology category. The first clearance was granted in 2015, with the most recent in 2023. This represents a historical regulatory record; the company has not pursued new FDA 510(k) submissions in recent years. INVOcell Intravaginal Culture System is the compa...

REGULATORY CONSULTANT

Consulting firm	**Avania, LLC**
Contact	Wanda Carpinella

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

CLINICAL EVIDENCE - NCT05189405

3 Year Retrospective Analysis of IVF in Comparison With INVOcell

Status	Unknown - *No results published to ClinicalTrials.gov*
Enrollment	450 patients (estimated)
Study sites	4 sites
Condition studied	Infertility
Study type	Observational
Completion date	Feb 28, 2022
Sponsor	INVO Bioscience, Inc. (Industry)

Primary outcome

Embryo development

Secondary outcome

Maternal Adverse Events

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05189405