FDA 510(k) Premarket Notification

K193330 Clue Birth Control

CLEARED

Feb 18, 2021
444 days to decision

K193330 · Product code: **PYT** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k193330/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Device, Fertility Diagnostic, Contraceptive, Software Application (PYT)
Date received	Dec 2, 2019
Decision date	Feb 18, 2021
Days to decision	444 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biowink GmbH**
Location	Berlin, DE
Contact	Carrie Walter
510(k) history	1 submissions · 1 cleared · 2021-2021

CLINICAL EVIDENCE - NCT02833922

Effectiveness and Efficacy of Dynamic Optimal Timing, a Smart Phone App for Avoiding Pregnancy: an Observational Study

Status	Completed
Enrollment	718 patients (actual)
Condition studied	Desire to Avoid Pregnancy
Study type	Observational
Completion date	Sep 30, 2019
Sponsor	Georgetown University (Other)

Primary outcome

Pregnancy Rates

Secondary outcome

Intent to Continue Using the Method at Study Completion

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02833922