

K200163 Ava Fertility TrackerJan 19, 2021
363 days to decisionK200163 · Product code: **LHD** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k200163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Fertility Diagnostic, Proceptive (LHD)
Date received	Jan 22, 2020
Decision date	Jan 19, 2021
Days to decision	363 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ava AG
Location	Zurich, CH
Contact	Blathnaid Feldman
510(k) history	1 submissions · 1 cleared · 2021-2021

CLINICAL EVIDENCE - NCT03161873

Cycle and Pregnancy Monitoring With Wearable Sensor Technology (AVA)

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	194 patients (actual)
Study sites	1 site
Condition studied	Fertility Disorders; Early Pregnancy
Study type	Observational
Completion date	Nov 1, 2020
Sponsor	University of Zurich (Other)

Primary outcome

Correlation between the physiology and the menstrual cycle dynamics

Secondary outcome

Correlation between the physiology measured using a wearable device and the occurrence of pregnancy

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03161873