FDA 510(k) Premarket Notification

K243851 CHLOE BLAST

CLEARED

Aug 15, 2025
242 days to decision

K243851 · Product code: **PBH** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k243851/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Embryo Image Assessment System, Assisted Reproduction (PBH)
Date received	Dec 16, 2024
Decision date	Aug 15, 2025
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fairtility , Ltd.**
Location	Tel-Aviv, IL
Contact	Maya Baranes Zeevi
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Sfadc, LLC**
Contact	Susan Alpert

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

CLINICAL EVIDENCE - NCT05455281

Performance of CHLOE Algorithm on the Prediction of Blastocyst Formation

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	55 patients (actual)
Study sites	3 sites
Condition studied	Fertility Disorders
Study type	Observational
Completion date	Jul 27, 2023
Sponsor	Fairtility (Industry)

Primary outcome

The association between the adjunct prediction using CHLOE of blastocyst outcome and the actual blastocyst outcome for a subset of good/fair embryos

Secondary outcome

The association between the adjunct prediction using CHLOE of blastocyst outcome and the actual blastocyst outcome for all embryos

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05455281