May 15, 2026

Alife Health
% Cindy Domecus
Principal
Domecus Consulting Services LLC
1171 Barroilhet Drive
Hillsborough, California 94010

Re: K250781
Trade/Device Name: Embryo Predict
Regulation Number: 21 CFR 884.6195
Regulation Name: Assisted Reproduction Embryo Image Assessment System
Regulatory Class: II
Product Code: PBH
Dated: March 16, 2026
Received: March 16, 2026

Dear Cindy Domecus:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: The Center for Devices and Radiological Health (CDRH) does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

SHARON M. ANDREWS -S

for Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology, and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250781

Device Name
Embryo Predict

Indications for Use *(Describe)*
Embryo Predict is indicated to analyze images of Day 5, 6, and 7 blastocyst-stage embryos (early, expanded, hatching, and hatched) cultured in vitro that have been deemed suitable for transfer by the embryologist.

The device uses patient metadata (patient age, day of embryo culture) and a software algorithm to analyze features of the blastocyst morphology and provides adjunctive information to aid in the assessment of blastocysts when there are multiple embryos deemed suitable for transfer or freezing based on standard morphological assessment.

The device is intended for analysis of blastocyst stage embryos prior to biopsy and cryopreservation.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY - K250781

Submitter Information

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Date Summary Prepared: May 15, 2026

Device Information

Device Trade Name: Embryo Predict
Common Name: Assisted Reproduction Embryo Image Assessment System
Regulatory Class: II
Regulation Name: Assisted Reproduction Embryo Image Assessment System
Regulation Number: 21 CFR 884.6195
Product Code: PBH

Legally Marketed Predicate Device

Predicate #: K142147
Predicate Trade Name: Eeva System
Product Code(s): PBH

The predicate device has not been subject to a design-related recall

Device Description

Embryo Predict is a software as a medical device (SaMD) that analyzes images of Day 5, 6, and 7 blastocyst-stage embryos (early, expanded, hatching, and hatched) that have already been determined to be suitable for transfer by an embryologist. The device uses patient metadata (patient age, day of embryo culture) and a software algorithm to analyze features of blastocyst

morphology to aid in the assessment of embryos for transfer when there are multiple embryos deemed suitable for transfer or freezing based on standard morphological assessment.

The device is intended for analysis of blastocyst stage embryos prior to biopsy and cryopreservation.

The product incorporates the following components: (1) system software for patient case management, image capture and storage, user interface, and a data framework for case data and software logging, and (2) image analysis algorithms, based on convolutional neural networks, that assess morphological features of an embryo image.

Indications for Use

Embryo Predict is indicated to analyze images of Day 5, 6, and 7 blastocyst-stage embryos (early, expanded, hatching, and hatched) cultured in vitro that have been deemed suitable for transfer by the embryologist.

The device uses patient metadata (patient age, day of embryo culture) and a software algorithm to analyze features of the blastocyst morphology and provides adjunctive information to aid in the assessment of blastocysts when there are multiple embryos deemed suitable for transfer or freezing based on standard morphological assessment.

The device is intended for analysis of blastocyst stage embryos prior to biopsy and cryopreservation.

Comparison of Intended Use and Technological Characteristics of the subject and predicate device

Device & Predicate Device(s):	**Subject Device** K250781	**Predicate Device** K142147
General Device Characteristics		
Device Name	Embryo Predict	Eeva System
Manufacturer	Alife Health	Auxogyn, Inc.
Principles of Operation	Assisted reproductive software application that analyzes images of embryos obtained using a standard inverted microscope, in combination with patient metadata, to assess morphological features and provide adjunctive information to aid embryologist assessment when selecting embryos for transfer.	Assisted reproductive microscope placed in a standard (3rd party) incubator that captures time-lapse embryo images, and automatically evaluates cell division timing parameters to predict whether an embryo has a High"/"Low" probability to reach the blastocyst stage.

Indications for Use	Embryo Predict is indicated to analyze images of Day 5, 6, and 7 blastocyst-stage embryos (early, expanded, hatching, and hatched) cultured in vitro that have been deemed suitable for transfer by the embryologist. The device uses patient metadata (patient age, day of embryo culture) and a software algorithm to analyze features of the blastocyst morphology and provides adjunctive information to aid in the assessment of blastocysts when there are multiple embryos deemed suitable for transfer or freezing based on standard morphological assessment. The device is intended for analysis of blastocyst stage embryos prior to biopsy and cryopreservation.	The Eeva System is indicated to provide adjunctive information on events occurring during the first two days of development that may predict further development to the blastocyst stage on Day 5 of development. This adjunctive information aids in the selection of embryo(s) for transfer on Day 3 when, following morphological assessment on Day 3, there are multiple embryos deemed suitable for transfer or freezing. The device may also be used to collect additional time-lapse images until Day 5 of development for embryos not selected for transfer, to allow monitoring of continued embryo development.
Conditions of Use	Prescription use only device used by embryologists and other trained IVF professionals in an IVF laboratory.	Prescription use only device installed in an IVF laboratory and used by embryologists and other IVF professionals.
Algorithm Deign	QC Model: A CNN model for image conversion, resizing, and normalization. Image Cropping Model: A UNet CNN model for image flattening, cropping, resizing, and brightness normalization. Image Classification Model: A CNN ensemble including 6 models for image processing and image score generation. Metadata Model: A logistic regression model using image score patient age, donor-egg status, and day of embryo culture to generate a final AI score.	Cell tracking and event inference used as algorithm inputs until Day 3 (68 hours).
Hardware Design and Materials	Subject device consists of a stand-alone software component used to	Standard computer, touchscreen monitors, electronics and optics;

	analyze images of embryos and patient metadata (no hardware components).	industry standard materials such as metals and plastics.
Device Outputs	AI Score: continuous score from 0 to 1 representing algorithm-derived assessment of embryo characteristics; provided as adjunctive information to aid embryologist assessment (not a direct prediction of clinical pregnancy)	"High" or "Low"

The subject and predicate device have different indications for use statements; however, they have the same intended use - to provide adjunctive information to assist the embryologist in selecting embryos for transfer.

The subject and predicate device have different technological characteristics, including different software/algorithm design, device outputs, and hardware. The subject device is software only, whereas the predicate device also includes hardware. These differences do not raise different questions of safety and effectiveness.

Non-Clinical Performance Testing

The following pre-clinical assessments were performed for the subject device:

Devices classified under 21 CFR 884.6195 (Assisted Reproduction Embryo Image Assessment System) and product code PBH must address several non-clinical special controls, including software validation, verification, and hazard analysis, an assessment of light exposure and output, simulated use, cleaning and disinfection, package integrity and transit testing, electrical safety and electromagnetic compatibility testing, and prediction algorithm reproducibility.

As Embryo Predict is a software, some of the special controls do not apply to this submission.

Software

Software was evaluated at the Basic Documentation level as recommended in the 2023 FDA guidance document "Content of Premarket Submissions for Device Software Functions". Software verification, validation, hazard analysis, and algorithm performance testing were conducted to demonstrate that the software performs as intended for its specified use environment.

Cybersecurity

Cybersecurity testing and documentation were provided for the Embryo Predict System in accordance with FDA's "Cybersecurity in Medical Devices" guidance and section 524B of the

FD&C Act. The Embryo Predict System incorporates cybersecurity controls including multi-factor authentication (MFA), TLS 1.3 encryption for communications, endpoint antivirus and anti-malware protection, role-based access controls, and cloud-based security protections. The System utilizes encrypted communication channels across cloud services, APIs, and associated infrastructure to protect the confidentiality and integrity of patient data.

Cybersecurity verification activities included threat modeling, verification testing, and penetration testing of the final software version. The testing demonstrated that implemented cybersecurity controls function as intended and support secure system operation within the intended use environment.

Algorithm validation/calibration curve

Algorithm calibration analyses were performed using external datasets from U.S.-based clinical sites that were not used for model training or tuning. The analyses demonstrated a generally monotonic relationship between increasing Embryo Predict scores and observed clinical pregnancy outcomes across the clinically relevant score range, supporting the interpretability and consistency of the algorithm output within the intended adjunctive workflow. Confidence interval analyses were also performed to evaluate uncertainty across score bins.

Clinical Performance Testing

The effectiveness of the Embryo Predict as an aid in adjunctively selecting an embryo for transfer has been evaluated in the ROVER and LOTUS clinical studies conducted by Alife Health. The LOTUS study also evaluated the safety of the Embryo Predict.

LOTUS RCT

Study design: The LOTUS study was a prospective, multi-center, randomized controlled clinical trial conducted at 7 sites in the United States. Subjects were randomized to either embryo selection using the traditional morphology grade (TM Arm) applicable to each site or adjunctive embryo selection using the Embryo Predict device (Embryo Predict Arm) in addition to traditional morphology grade.

Subjects were randomized in a 1:1 ratio to the TM or TM with Embryo Predict Arms. Age stratification blocks were used to balance across age groups. Additionally, stratification by site and PGT-A (Preimplantation Genetic Testing for Aneuploidy) status was also performed.

After randomization, embryo selection was performed only on those subjects that had multiple embryos already deemed suitable for transfer based on traditional morphology grade.

Embryo selection for the TM Arm was based on morphologic appearance on Day 5, 6, or 7 according to each site's embryologist's standard practice of morphology grading method. Only this standard morphology grade was used to determine the most suitable embryo for transfer.

Embryo selection for the Embryo Predict Arm was based on the embryologist utilizing the Embryo Predict System score to determine the most suitable embryo for transfer (i.e., after traditional morphology was already completed). In the event the embryologist or clinician deemed it necessary to over-ride the Embryo Predict score (i.e. transfer an embryo that was not the highest Embryo Predict rank), they had the ability to make the transfer based on their traditional morphology assessment/grade.

Study Population: Subjects were identified and recruited at each of the IVF clinics participating in the study. Enrolled subjects were those already undergoing in vitro fertilization treatment with a planned transfer and meeting all eligibility criteria. A total of 444 subjects were enrolled in the study. There were no statistically significant differences in subject demographics, baseline hormones, stimulation protocol, cycle outcomes, and transfer characteristics of the subjects in the mITT analysis population between the two arms.

Primary effectiveness endpoint: The primary effectiveness endpoint for the LOTUS study was clinical pregnancy, defined as the presence of a fetal heartbeat at a 6-8 week gestation ultrasound.

Primary safety endpoint: The primary safety endpoint was the number and percentage of any device-related adverse events.

Secondary endpoints:

1. Incidence of disagreement for the top-ranked embryo between the Embryo Predict System (highest Embryo Predict score) and the embryologist (Traditional Morphology grading as conducted by the embryologist).
2. Assessment of Embryo Predict System usability as reported by the embryologist using a standardized user questionnaire.

Analysis Populations: There were four distinct analysis populations:

1. **The Intention-to-Treat (ITT)** population consisted of all randomized women who underwent an embryo transfer.
2. **The Modified Intent-to-Treat (mITT)** population consisted of all randomized women who are part of the ITT population, had an embryo selected with either study method, and either (1) underwent an embryo transfer and PGT-A results showed at least 2 euploid blastocysts available or (2) did not have PGT-A results for their embryo transfer and had 2 or more blastocysts available. The mITT analysis population was used as the primary analysis population for the primary effectiveness endpoint.

3. **Per Protocol (PP)** population consisted of all women in the mITT population without protocol deviations that would impact study outcomes.
4. **Randomization Adherent Population (RAP)** consists of subjects in the mITT analysis population who had embryo transfer based on the selection method assigned at randomization – TM or Embryo Predict.

RESULTS

The table below provides a summary of the LOTUS study sites in terms of experience, volume of IVF cycles per year and number of embryologists per site.

Demographics of LOTUS Study Sites

Site	Total Years Site Operating	Cycles/Year	# of Embryologists
01	41 years	4,500	17
02	40 years	1,500	10
03	16 years	1,900	9
04	35 years	900-1,000	6
05	29 years	~750	3
06	39 years	>2,000	8
07	8 Years	1,200	7

Two of the clinical study sites (Site 02 and Site 06) also provided data for algorithm training, validation, and testing; however, these training and validation data were completely independent of the data collected in the LOTUS study. Data from model development were collected from 2015- 2020 and the LOTUS study was performed from 2022-2024.

Furthermore, to address a concern for bias, an analysis using all imaged embryos with outcomes from the Intent to Treat (ITT) population from the LOTUS study was performed.
The analysis stratified the data into two groups: sites that contributed data to the algorithm development and new sites that did not contribute to algorithm development.

The Area Under the Curve (AUC) was calculated separately for each group to assess the algorithm's performance. The results (see Tables 6 and 7 below) demonstrates that the AUC and OR is the same for both groups, indicating the performance of Site 02 and Site 06 has the same performance as new sites that did not contribute data to algorithm development.

AUC comparison for Site 02 and Site 06 compared to sites that did not contribute data to algorithm development (ITT)

Site	Area under ROC Curve (AUC)

Site 02 and Site 06	0.72
Other sites	0.73

OR of Sites 02 and 06 compared to sites that did not contribute data to algorithm development

Site	Site 02 and Site 06	Other Sites
OR	1.59 (95% CI: 1.31, 1.93)	1.57 (95% CI: 1.34, 1.84)

The study enrolled 444 subjects with 283 evaluable in the mITT population. Demographics for the mITT population (n = 283) are presented in the table below. Subject demographics were well balanced between the traditional morphology (TM) arm (N=150) and the Embryo Predict arm (N=133). Distributions of race and ethnicity were similar across arms, with no statistically significant differences observed (race p=0.800; ethnicity p=0.870). The mean age of subjects was comparable between groups (33.7 ± 3.9 years in the TM arm vs. 33.9 ± 3.8 years in the Embryo Predict arm), as was body mass index (27.9 ± 6.3 kg/m² vs. 27.3 ± 6.3 kg/m²), with no significant between-group differences. Overall, baseline demographic characteristics were comparable between treatment arms, supporting the validity of between-group comparisons.

Subject Demographics – mITT Population (N = 283)

Subject Demographics		TM (N = 150)	Embryo Predict (N =133)	P-value
Race	Asian	20 (13.3%)	15 (11.3%)	0.800
	Black or African American	8 (5.3%)	8 (6.0%)	
	Caucasian or white	66 (44.0%)	67 (50.4%)	
	Other/Unknown	50 (33.3%)	37 (27.8%)	
	Refused to Answer	6 (4.0%)	6 (4.5%)	
Ethnicity	Hispanic or Latino	16 (10.7%)	17 (12.8%)	0.870
	Not Hispanic or Latino	83 (55.3%)	71 (53.4%)	
	Other/Unknown	37 (24.7%)	30 (22.6%)	
	Refused to Answer	14 (9.3%)	15 (11.3%)	
Age (Years)	Mean ± SD	33.7 ± 3.9	33.9 ± 3.8	0.562
	Median	34.0	34.0	
	25^{th}, 75^{th} percentile	31.0, 37.0	31.0, 37.0	
	Min, Max	22, 42	23, 42	
BMI (kg/m^2)	Mean ± SD	27.9 ± 6.3	27.3 ± 6.3	0.391
	Median	27.1	25.5	
	25^{th}, 75^{th} percentile	22.7, 32.1	22.0, 31.6	
	Min, Max	15, 43	18, 44	

Primary Effectiveness Endpoint: The Embryo Predict clinical pregnancy rate for the mITT population was 72.9% (97/133), and the Traditional Morphology (TM) Control Arm clinical

pregnancy rate was 68.0% (102/150). Based on these clinical pregnancy outcome rates, the Embryo Predict Arm is non-inferior to the TM Arm (p=0.003), see table below.

Clinical Pregnancy Rate for mITT Analysis Population – Primary Endpoint

	TM (N=150) (95% CI*)	Embryo Predict (N=133) (95% CI)	Difference (95% CI*)	P-Value**
Clinical Pregnancy (6 to 8 week Ultrasound)	102/150 (68.0%) (60.2%, 75.0%)	97/133 (72.9%) (64.8%, 79.8%)	4.9% (-5.7% to 15.6%)	0.003

**Wilson Confidence Intervals*
***P-values based on a binomial test for non-inferiority with a 10% NI margin.*

Secondary Effectiveness Endpoints:

1. In the Embryo Predict Arm, there were 25/133 (18%) embryos where the highest Embryo Predict score was not selected for transfer. Among these override cases, 13 involved selection of an embryo whose Embryo Predict score differed by ≥0.1 from the highest-scoring embryo, resulting in a clinical pregnancy rate of 77%. In the remaining 12 override cases—where the selected embryo's score was within 0.1 of the highest Embryo Predict score—the observed clinical pregnancy rate was 75%. These findings indicate that embryologists exercised clinical judgment both in near-tie scenarios and in cases of larger score separation, without an apparent adverse impact on pregnancy outcomes.
2. Usability assessments demonstrated that the majority of embryologists found Embryo Predict easy to operate and interpret, and most indicated they would use the Embryo Predict score for future patients. No embryologist indicated unwillingness to use the System.

Primary Safety Endpoint:

There were zero device-related adverse events reported in the study.

The clinical pregnancy rates based on subgroup analyses for age and day of culture are summarized below.

Clinical Pregnancy Rate by Age Subgroups

Age Group	TM (N=150) (95% CI*)	Embryo Predict (N=133) (95% CI*)
<35	59/86 (68.6%) (58.2%, 77.4%)	59/77 (76.6%) (66.1%, 84.7%)

35-37	26/36 (72.2%) (56.0%, 84.2%)	17/27 (62.9%) (44.2%, 78.5%)
>37	17/28 (60.7%) (42.4%, 76.4%)	21/29 (72.4%) (54.3%, 85.3%)

**Wilson Confidence Intervals*

Clinical Pregnancy Rate by Day of Culture Subgroup

Day of culture	**TM (N=150) (95% CI*)**	**Embryo Predict (N=133) (95% CI*)**
Day 5	75/110 (68.2%) (59.0%, 76.2%)	77/102 (75.5%) (66.3%, 82.8%)
Day 6 or 7	27/40 (67.5%) (52.0%, 79.9%)	20/31 (64.5%) (47.0%, 78.9%)

**Wilson Confidence Intervals*

Microscopes/Cameras Used in Study: Since the number of patients imaged using certain microscope and camera brands in the LOTUS study was limited, to improve the robustness and reliability of the analysis, the brands of the individual microscopes and cameras were combined. For example, all the Olympus microscopes (IX-73, IX-71, and IX-70) were combined for the Area Under the Curve (AUC) analysis as one brand. Similarly, the same was done for the camera brand, where the WATEC camera brand was combined for the AUC analysis. This analysis was performed using the mITT population, restricted to the combined microscope and camera brands. This approach provides a representation of the algorithm's performance across hardware configurations and ensures alignment with the device's intended use and labeling. The table below provides the performance metrics using the mITT population with the combined Microscope and Camera brands.

Performance metrics for combined microscope/camera brands (mITT)

Microscope/Camera Brand	Microscope/Camera	Area under ROC Curve (AUC)	Number of Patients
Olympus	Microscope	0.74	109
WATEC	Camera	0.72	94
EmbryoScope	Microscope/Camera	0.81	23

ROVER Retrospective Reader Study

Study Design: This was a retrospective, double-blinded, randomized comparative reader study to compare the performance of the Embryo Predict Algorithm to embryologists using traditional morphological grading in selecting the top embryo for transfer in simulated patient embryo panels. The embryologist readers were blinded to the Embryo Predict score and clinical pregnancy outcome data when selecting an embryo for transfer and the algorithm team generating the Embryo Predict score were blinded to the pregnancy outcome data and the traditional morphology grade (only day of development was available to the team).

Randomization for this study was implemented in two ways. First, assignment of the embryos into the patient panels was randomized from within bins defined by age category, race, and PGT status, and secondly the order of the patient panels presented to the embryologist was randomized between each embryologist reader. For each simulated patient panel, the Embryo Predict algorithm selected the top ranked embryo using the embryo image and the five participating embryologists (with varying experience levels) also each selected the top embryo from each patient panel using the traditional morphology score.

Study Population (Simulated Patient Panels): Simulated patient panels were created from the individual embryos. Every simulated patient panel in the study had a unique set of embryos. Each embryo was randomly distributed to a patient panel, where no two patient panels contained more than one common embryo.

Primary Effectiveness Endpoint: Comparison of clinical pregnancy outcomes between the Control Arm and Treatment Arm. Clinical pregnancy defined as fetal heartbeat by ultrasound after 6-8 weeks gestation. An embryo selected using the Embryo Predict Algorithm score will have a non-inferior chance of clinical pregnancy after the transfer of the first blastocyst compared to a blastocyst selected solely by the embryologist morphologic assessment.

Secondary Effectiveness Endpoints:

1. Incidence where embryo selection in the control group was a random choice between identical embryos.

2. Inter-Rater variability amongst the five embryologist readers.

3. Incidence where top embryo for selection differed between the Traditional Morphology Arm and the Embryo Predict Arm.

RESULTS

A total of 1,257 simulated patient panels were created from 438 individual embryos with morphology grades and known outcomes, matching embryo cohorts based on age, PGT status, and race.

Five (5) embryologists participated as readers, representing 5 sites. Each embryologist independently reviewed all 1,257 patient panels, selecting a single embryo for each panel (through consensus) that they would prioritize for transfer using TM alone. All readers completed all assessments, with no missing data.

The table below summarizes the demographics of the 438 embryos that were utilized in the creation of the patient panels. The average age of the embryos was 33.6 (±4.1) years. Nearly half (47.3%) of the embryos were derived from white subjects. The overall clinical pregnancy rate was 62.6% (274/438). The majority of the embryo images were captured on Day 5 (72.1%), and approximately half (52.5%) of the embryos were confirmed Euploid by PGT.

Embryo Demographics

Demographic	Embryos (N=438)
Age (Years)	
Mean	33.6
SD	4.1
Min, Max	21, 46
Age Category	
18 to <30	15.5% (68/438)
≥30 to <34	33.6% (147/438)
≥34 to <38	33.8% (148/438)
≥38	17.1% (75/438)
Race	
White	47.3% (207/438)
Non-White	28.3% (124/438)
Unknown	24.4% (107/438)
Day of Image Capture	
Day 5	72.1% (316/438)
Day 6	27.4% (120/438)
Day 7	0.5% (2/438)
PGT Status	
Euploid	52.5% (230/438)
Untested	47.5% (208/438)
Clinical Pregnancy Rate	
Pregnant	62.6% (274/438)

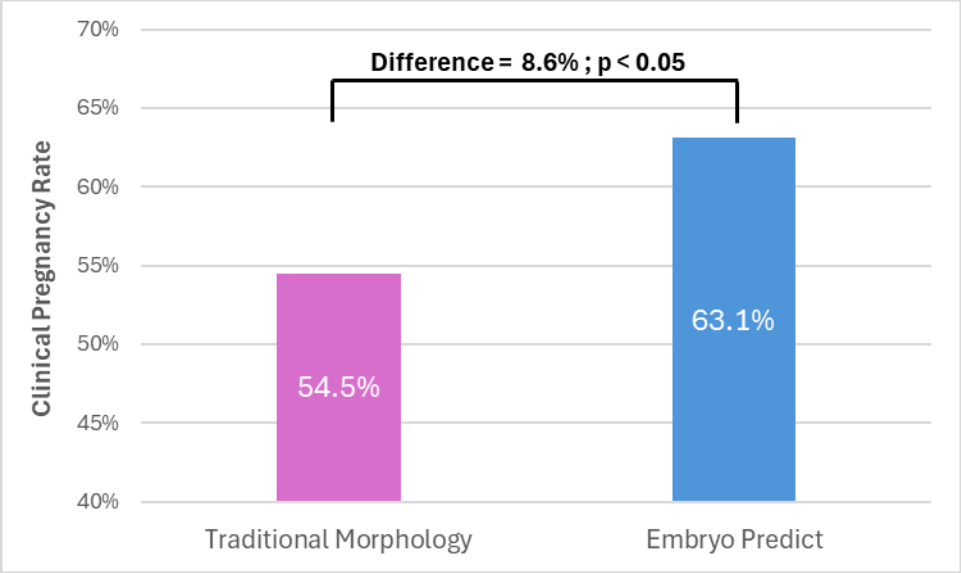
Demographic	Embryos (N=438)
Not-Pregnant	37.4% (164/438)

The primary effectiveness endpoints, i.e., the clinical pregnancy rate for embryos selected by the Embryo Predict algorithm was 62.3%, while the average pregnancy rate of the top embryos selected by the participating embryologists was 61.0%, meeting the study's success criterion of noninferiority ($p<0.05$).

Arm	Clinical Pregnancy Rate	95% Confidence Intervals
Embryo Predict Algorithm (Treatment Arm)	62.3% (783/1257)	(59.6%, 65.0%)
Traditional Morphology (Control Arm)	61.0% (3832/6285)	(58.6%, 63.4%)

	Difference	95% Confidence Intervals	Non-Inferiority P-Value
Embryo Predict Algorithm vs All 5 Embryologists Combined	1.3%	(-1.3%, 3.9%)	**<0.001**

Secondary Effectiveness: In the instances where there was consensus amongst all five embryologists on the top embryo for transfer, the Embryo Predict algorithm disagreed in 31% of the decisions. In the subset of cases where there was consensus amongst all five embryologists and the Embryo Predict disagreed with the consensus, the Embryo Predict Algorithm achieved a statistically significant improvement of 8.6% in clinical pregnancy rate compared to the embryologist consensus on top embryo for transfer (TM: 139/255 (54.5%), Embryo Predict 161/255 (63.1%) ($p < 0.05$), see figure below.



Clinical Pregnancy Rates When Embryo Predict and Embryologist Consensus Disagreed

In 5.7% of patient panels (72/1,257), embryologists were unable to distinguish between embryos based on morphology because two or more embryos were graded identically. In these cases, selection was effectively random, underscoring the inherent limitations of morphology-based decision-making in certain scenarios. In this subset of patient panels, the clinical pregnancy rate associated with embryo selection by traditional morphology across the five embryologist reviews was 50.0% (36/72), compared to 56.9% (41/72) when the embryo was selected based on the Embryo Predict algorithm, corresponding to a 6.9% absolute difference in favor of Embryo Predict (see table below).

Identical Morphology Embryos in Patient Panels

Arm	Clinical Pregnancy Rate (N=72) (95% CI*)
Traditional Morphology (Control)	50.0% (36/72) (38.8%, 61.3%)
Embryo Predict Algorithm (Treatment)	56.9% (41/72) (45.4%, 67.7%)

**Wilson Confidence Intervals*

When examined on an individual embryologist basis within panels where disagreement occurred, Embryo Predict demonstrated higher clinical pregnancy rates compared to four (4) of the five (5) embryologists (see table below). Numerically and statistically significant improvements were observed relative to Embryologist 2 (59.2% vs. 51.8%; +7.4%, $p < 0.05$) and Embryologist 3 (60.4% vs. 52.0%; +8.4%, $p < 0.01$). For Embryologists 1 and 5, Embryo Predict showed numerical improvements of 2.2% and 1.9%, respectively, though these differences were

not statistically significant. Only one embryologist (Embryologist 4) demonstrated a higher clinical pregnancy rate than the Embryo Predict algorithm, with a 2.9% difference that was not statistically significant. Overall, these findings indicate that, in cases where embryo selection decisions diverged, Embryo Predict generally performed as well as or better than individual experienced embryologists, with numerically and statistically significant improvements observed for two readers.

Clinical Pregnancy Rates When There was Disagreement Between Embryologist and Embryo Predict Algorithm

Embryologist	N	Traditional Morphology (TM) Clinical Pregnancy Rate	Embryo Predict Algorithm Clinical Pregnancy Rate	Difference between Embryo Predict and TM	P-Value*
Embryologist 1	456	56.4% (257/456)	58.6% (267/456)	2.2%	0.502
Embryologist 2	461	51.8% (239/461)	59.2% (273/461)	7.4%	**<0.05**
Embryologist 3	512	52.0% (266/512)	60.4% (309/512)	8.4%	**<0.01**
Embryologist 4	448	59.6% (267/448)	56.7% (254/448)	-2.9%	0.379
Embryologist 5	456	56.4% (257/456)	58.3% (266/456)	1.9%	0.546

*P-values are *nominal* and correspond to prespecified secondary analyses. The study was not adequately powered for superiority and no multiplicity adjustment was applied; therefore, statistical significance cannot be inferred from these p-values.

Inter-rater variability among embryologists was observed in 34.6% of patient panels (435/1,257). When panels included three or more embryos, disagreement increased to 43.9%.

No safety concerns were identified, as this was a retrospective study involving no patient intervention.

The device was not evaluated using embryologists with a range of experience and the results may not reflect real world performance across community-based embryology clinics in the US. The data collected and provided does not support improved clinical pregnancy outcomes when using the subject device compared to standard of care.

Conclusion

The non-clinical and clinical performance data described above demonstrate that the Embryo Predict is as safe and effective as the predicate device and supports a determination of substantial equivalence.