November 15, 2017

Genea Biomedx Pty Ltd
% Roger Gray
VP, Quality Assurance and Regulatory Affairs
Donawa Lifescience Consulting Srl
Piazza Albania 10
00153 Rome
Italy

Re: K171736
Trade/Device Name: Geri Embryo Incubator and Geri Dish
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulatory Class: II
Product Code: MQG, MQK, MTX
Dated: October 12, 2017
Received: October 16, 2017

Dear Roger Gray:

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 (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. 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: 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, FDA may publish further announcements concerning your device in the Federal Register.

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 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171736

Device Name
Geri Embryo Incubator and Geri Dish

Indications for Use *(Describe)*
The Geri Embryo Incubator is intended to provide an environment with controlled temperature and mixed gas (CO2 and other gases) for the development of embryos. The Geri Embryo Incubator has an integrated camera and optics for imaging and viewing embryos during incubation, for a maximum time of 120 hours.

The Geri Dish is intended to be used for preparation, storage and imaging of human embryos. The Geri Dish is intended to be used only with the Geri Embryo Incubator.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
(K171736)

I. General Information on Submitter

Submitter/Address:	Genea Biomedx Pty Ltd Level 2, 321 Kent Street Sydney NSW 2000 Australia
Contact person:	Ms. Kea Dent
Phone:	+61 2 8484 7677
Fax:	+61 2 9229 6478
Correspondent:	Mr. Roger Gray VP, Quality and Regulatory Donawa Lifescience Consulting Srl Piazza Albania 10 00153 Rome Italy
Phone:	+39 06 578 2665
Fax:	+39 06 574 3786
Email:	rgray@donawa.com

II. Date Prepared:
November 14, 2017

III. General Information on Devices

Device Name:	Geri Embryo Incubator and Geri Dish
Common Name:	Embryo Incubator
Classification Name:	Assisted Reproduction Accessories (21 CFR 884.6120)
Product code:	MQG (Accessory, Assisted Reproduction), MQK (Labware, Assisted Reproduction, MTX (Microscope and Microscope Accessories, Reproduction, Assisted)
Regulatory Class:	II

IV. Predicate Device

EmbryoScope (Version D) and EmbryoViewer Software (K113075) and EmbryoScope and EmbryoSlide (K092183), which are manufactured by Unisense FertiliTech A/S. The predicate devices have not been subject to any design related recalls.

V. Device Description

The Geri Embryo Incubator is a benchtop incubator with six modular incubation chambers each with its own temperature control capability and separate gas inlet feed. Each chamber contains heating elements in its lid and base, together with an orange light source (591 nm) and camera with integrated optics that take time-lapse images of embryos and allows operators to view embryos without removing them from the incubation chamber. Inside each chamber is a filter used to filter the gas mixture entering the incubation chamber from the gas supply. The gas is supplied from standard premixed medical gas cylinders.

The Geri Embryo Incubator includes firmware to control the incubator settings, and software to control patient information and settings.

The embryos are maintained in Geri Dishes that are supplied separately. The Geri Dish is an optically-clear polystyrene dish designed to be compatible with the Geri Embryo Incubator. Up to 16 embryos can be stored in one Geri Dish. Geri Dishes are supplied sterile with a sterility assurance level (SAL) of 10^{-6}, and have a shelf-life of 12 months.

The Geri Embryo Incubator and Geri Dish are intended to be used together for embryo imaging purposes. The Geri Dish is not compatible with other embryo time-lapse incubators. However, other assisted reproduction culture dishes may be used in the Geri Embryo Incubator in separate non-time-lapse positions located within each chamber.

VI. Indications for Use:

The Geri Embryo Incubator is intended to provide an environment with controlled temperature and mixed gas (CO2 and other gases) for the development of embryos. The Geri Embryo Incubator has an integrated camera and optics for imaging and viewing embryos during incubation, for a maximum time of 120 hours.

The Geri Dish is intended to be used for preparation, storage and imaging of human embryos. The Geri Dish is intended to be used only with the Geri Embryo Incubator.

VII. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices

Comparison of Geri Embryo Incubator with predicate device

Device/Predicate Devices	Subject device – Geri Embryo Incubator	Predicate device – EmbryoScope (Version D) and EmbryoViewer Software (K113075)
Indications for Use	The Geri Embryo Incubator is intended to provide an environment with controlled temperature and mixed gas (CO_2 and other gases) for the development of embryos. The Geri Embryo Incubator has an integrated camera and optics for imaging and viewing embryos during incubation, for a maximum time of 120 hours.	The Embryoscope (Version D) provides an environment with controlled temperature, CO_2 (and other gases) for the development of embryos. This model has an integrated inverted microscope and imaging system for embryo viewing. Device use is limited to five days (120 hr) covering the time from post-fertilization to day 5 of development. EmbryoViewer is an optional accessory software package for use in displaying, comparing, storing, and transferring EmbryoScope (Version D) generated images. The software includes a user annotation function for capturing information on embryo development parameters, treatment data, and outcome data. The EmbryoViewer software does not control any hardware components in the EmbryoScope (Version D) device.
Incubation chamber heating	Heated aluminium stage and lid	Heated chamber with recirculation
Incubation humidity	Same as predicate	No chamber humidification
Gas supply type	Premixed blend of 6% CO_2, 5% O_2, 89% N_2 or high purity 6% CO_2	Internally regulated mixture of CO_2, O_2 and N_2
Gas supply pressure	150 ± 15 kPa (218 ± 2.2 psi)	Unclear
Gas flow rate capability	10 mL/min per chamber. Purge at 160 mL/min per chamber for 3 min	Unclear
Gas flow rate accuracy	±15% of flow per chamber (normal flow) and ±10 mL/min per chamber (purge)	Unclear
HEPA Filter	Same as predicate	Retains 99.97% of particles >0.3 µm
Chamber temperature capability	35.0-40.0°C in 0.1°C increments at 20-28°C. At set point of 37°C, the ambient temperature range is 18-30°C	30-45 ± 0.2°C
Chamber temperature accuracy	±0.2°C at calibration point	During incubation ±0.1°C

Device/Predicate Devices	Subject device – Geri Embryo Incubator	Predicate device – EmbryoScope (Version D) and EmbryoViewer Software (K113075)
Microscope/camera	CMOS microscope camera (2560×1928 pixels monochrome)	CCD camera (1280×1024 pixels monochrome)
Image resolution	2 pixels/µm	3 pixels/µm
Image acquisition frequency	5 min	10 min
Illumination	Single orange LED (591nm)	Single red LED (635nm)
Number of image focal planes	11	7
Light exposure	~45s/day	Unclear
The subject and predicate devices have the same intended use – culturing embryos and capturing, storing and viewing embryo images. They also have the same fundamental technology – incubator with temperature and gas control and integrated microscope/camera for time-lapse imaging. There are differences in design and performance specifications between the subject and predicate devices. However, these differences do not raise different questions of safety and effectiveness.		

Comparison of Geri Dish with predicate device

Device/Predicate Devices	Subject device – Geri Dish	Predicate device – EmbryoSlide (K092183)
Indications for Use	The Geri Dish is intended to be used for preparation, storage and imaging of human embryos. The Geri Dish is intended to be used only with the Geri Embryo Incubator.	Preparing, storing, and transferring human embryos. To be used only with the EmbryoScope device.
Fundamental design	Same as predicate	Dish with multiple microwells intended to house individual embryos
Design feature	16 culture wells Well base diameter 0.43mm Well depth 0.4mm 3 outer rings for wash or rinse media Fill volume 40-80µl Optically clear with a lid	Unclear
Material	Same as predicate	Polystyrene
The subject and predicate devices have the same intended use – preparing and storing human embryos undergoing time-lapse imaging procedures. They also have the same fundamental technology – culture dishes with multiple small microwells intended to house individual embryos. The subject device is different from the predicate device regarding microwell number, dimensions, and fill volume. However, these differences do not raise different questions of safety and effectiveness.		

VIII. Summary of Non-clinical Performance Testing

The following studies have been performed to support substantial equivalence to the predicate devices:

Testing for Geri Embryo Incubator

- Electrical safety testing per IEC 61010-1:2010
- Electromagnetic Compatibility testing per IEC 61326-1:2012
- Software verification and validation testing that met the requirements of the FDA Guidance Document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document” issued on May 11, 2005
- Cleaning and disinfection validation testing per FDA Guidance Document, “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration” issued on March 17, 2015
- Bench performance tests that met design specifications described in Section VII, as follows:

Genea BIOMEDX

    * Gas maintenance testing to ensure that gas flow rates, gas recovery rates and CO_2 levels in chambers meet design specifications
    * Temperature control testing to ensure that culture chamber temperature conditions were within defined ranges and were stable over time.
    * Time-lapse testing to demonstrate that all design specifications of time-lapse function are met (dish presence detection, dish position accuracy, image quality and resolution, imaging of embryos in all wells on Geri Dishes within time and focal plane settings)
- Embryo development test demonstrating that ≥70% mouse 1-cell embryos developed to blastocyst on day 5 following exposure to the maximum time lapse exposure conditions.
- Embryo light energy exposure testing comparing the potential for light toxicity associated with time-lapse imaging under worst-case exposure conditions (maximum light exposure over the full duration of use [120 hours]) to that of total light exposure during in assisted reproduction procedures (IVF and ICSI) using typical laboratory microscopes. Results showed total light energy exposure following time-lapse imaging should not exceed levels associated with typical assisted reproduction imaging procedures.

Testing for Geri Dish

- Radiation sterilization validation testing per ISO 11137-2:2009
- Package integrity testing:
    * Dye Penetration Test per ASTM F1929-12
    * Peel strength testing ASTM F88/F88M-09
- Endotoxin testing per USP <85> and ANSI/AAMI ST72: 2011. The testing demonstrated that the device met the specification of <20 EU/device.
- Mouse embryo assay (MEA):

  One-cell mouse embryos were exposed to subject devices and cultured at 37°C in an atmosphere containing 5% CO_2. The percent of embryos developed to the expanded blastocyst stage within 96 hours were assessed in comparison with the control group. The testing demonstrated that the device met acceptance criterion of "1-cell MEA ≥80% embryos developed to blastocyst in 96 hours."
- Shelf-life testing (accelerated) demonstrating that visual requirements, media fill volume, time-lapse alignment and MEA met design specifications before and after aging

IX. Conclusion

The subject and predicate devices have the same intended use and fundamental technological characteristics. The differences in technological characteristics between subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.