April 20, 2018

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

Re: K180304
Trade/Device Name: Geri Embryo Incubator and Geri Dish
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: Class II
Product Code: MQG, MQK, MTX
Dated: March 19, 2018
Received: March 22, 2018

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -S

For 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)*
K180304

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.

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510(k) Summary
(K180304)

I. General Information on Submitter

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II. Date Prepared:

April 19, 2018

III. General Information on Devices

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

IV. Predicate Device

Geri Embryo Incubator (K171736) manufactured by Genea Biomedx, Australia. The predicate device has 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. Each chamber can also contain an optional water bottle (Geri Water Bottle) to generate humidity. The Geri Water Bottle is supplied sterile with a sterility assurance level (SAL) of 10^{-6}, and has a shelf-life of three years. The Geri Water Bottle is designed to be used with the Geri Embryo Incubator only.

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.

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

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 Device and Predicate Device

Parameter	Subject device (K180304)	Predicate device (K171736)
Indications for Use	Same as the predicate device	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.
Number of incubation chamber	Same as the predicate device	Six
Incubation chamber heating	Same as the predicate device	Heated aluminium stage and lid
Incubation chamber gas supply	Same as the predicate device	Flow controlled positive pressure system with fast purge flow rate for rapid recovery
Incubation chamber humidity	Disposable water bottle to generate humidity (~80% RH) in each incubation chamber	N/A
Gas supply type	Same as the predicate device	Premixed blend of 6% CO_2, 5% O_2, 89% N_2 or high purity 6% CO_2
Gas supply pressure	Same as the predicate device	150 ± 15 kPa (218 ± 2.2 psi)
Gas flow rate capability	Same as the predicate device	10 mL/min per chamber. Purge at 160 mL/min per chamber for 3 min
Gas flow rate accuracy	Same as the predicate device	±15% of flow per chamber (normal flow) and ±10 mL/min per chamber (purge)
HEPA Filter	Same as the predicate device	Retains 99.97% of particles >0.3 µm
Chamber temperature capability	Same as the predicate device	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
Chamber temperature accuracy	Same as the predicate device	±0.2°C at calibration point
Microscope/camera	Same as the predicate device	CMOS microscope camera (2560×1928 pixels monochrome)
Image resolution	Same as the predicate device	2 pixels/µm
Image acquisition frequency	Same as the predicate device	5 min
Illumination	Same as the predicate device	Single orange LED (591nm)
Number of image focal planes	Same as the predicate device	11
Light exposure	Same as the predicate device	~45s/day
Alarm (for out of range)	Same as the predicate device, with additional alarm for humidity	Chamber temperature, CO_2 concentration, CO_2 pressure O_2 concentration, N_2 pressure, Load door open >30s

Parameter	Subject device (K180304)	Predicate device (K171736)
Culture dish (Geri Dish)	Same as the predicate device	16-well culture dish (40-80 µl fill volume/well) made of polystyrene. Each incubation chamber can hold one dish

The subject and predicate devices have the same Intended Use for preparing and storing human embryos undergoing time-lapse imaging procedures. They also have the same technological characteristics, except that the subject device has an additional humidity control system, including a water container, humidity sensor, and software component to manage this new feature. The addition of humidification system to the device does not raise different questions of safety and effectiveness as compared to the predicate device. In addition, similar humidification systems are present on other cleared devices of this type.

VIII. Summary of Non-Clinical Performance Testing

1. The following studies that were provided in the predicate submission (K171736) were leveraged in the current submission as the additional humidity control system did not impact the ability of these studies to support substantial equivalence:

Testing for Geri Embryo Incubator

- Electrical safety testing per IEC 61010-1:2010
- Electromagnetic Compatibility testing per IEC 61326-1:2012
- 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:
    - Gas maintenance testing to ensure that gas flow rates, gas recovery rates and CO2 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 testing 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

2**.** The following studies on the subject device have been conducted to support the addition of the humidity control system to the Geri Embryo Incubator:

Testing for Geri Embryo Incubator:

- 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
- Humidity control testing to ensure that the humidity levels in chambers meet design specifications

Testing for Geri Water Bottle:

- Radiation sterilization validation testing per ISO 11137-2:2013
- Package integrity testing:
    - Dye penetration testing per ASTM F1929-15
    - Seal strength testing per ASTM F88/F88M-15

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.