June 7, 2018

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

Re: K180188
Trade/Device Name: Geri Embryo Incubator with Geri Connect and Geri Assess Software, and Geri Dish
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulatory Class: II
Product Code: MQG, MQK, MTX
Dated: May 7, 2018
Received: May 9, 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 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,

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180188

Device Name
Geri Embryo Incubator with Geri Connect and Geri Assess Software, 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.

Geri Connect and Geri Assess are optional software accessories for the Geri Embryo Incubator. Geri Connect is intended for access and review of time-lapse data generated by the Geri Embryo Incubator on a local area network. Geri Assess is intended for viewing and recording embryo development events from images captured using the Geri Embryo Incubator. Geri Assess includes a user annotation function for capturing information on embryo development parameters and a user-defined modeling function that allows the user to combine annotated information on embryo development parameters to aid in embryo selection. Geri Connect and Geri Assess do not control any hardware components in the Geri Embryo Incubator. Geri Connect and Geri Assess are combined in the same software package and must be used together.

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.

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# 510(k) Summary
## (K180188)

## I. General Information on Submitter


| | |
|---|---|
| Submitter/Address: | Genea Biomedx Pty Ltd<br>Level 2, 321 Kent Street<br>Sydney<br>NSW 2000<br>Australia |
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| Email: | rgray@donawa.com |


## II. Date Prepared

June 7, 2018

## III. General Information on Device

| | |
|---|---|
| Device Name: | Geri Embryo Incubator with Geri Connect and Geri Assess Software, 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 Devices

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

The Geri Assess and Geri Connect are optional software accessories for the Geri Embryo Incubator. The Geri Connect allows the user to access the embryo data remotely, whereas the Geri Assess provides the user with a tool for analysis of embryo data. Using user defined parameters, the Geri Assess can score the embryos. However, the Geri Assess itself does not include any pre-loaded scoring assessments or perform any diagnostic functions. The Geri Connect and Geri Assess software package is provided with the Geri Embryo Incubator, but needs to be unlocked, when purchased by the end user.

The Geri Dish is intended to be used for preparation, storage and imaging of human embryos. 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 Dish is intended to be used only with the Geri Embryo Incubator. 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 ($CO_2$ 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.

Geri Connect and Geri Assess are optional software accessories for the Geri Embryo Incubator. Geri Connect is intended for access and review of time-lapse data generated by the Geri Embryo Incubator on a local area network. Geri Assess is intended for viewing and recording embryo development events from images captured using the Geri Embryo Incubator. Geri Assess includes a user annotation function for capturing information on embryo development parameters and a user-defined modelling function that allows the user to combine annotated information on embryo development parameters to aid in embryo selection. Geri Connect and Geri Assess do not control any hardware components in the Geri Embryo Incubator. Geri Connect and Geri Assess are combined in the same software package and must be used together.

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

The Indications for Use for the Geri Embryo Incubator and Geri Dish are same as those for the predicate device. Unlike the predicate device, the subject device also includes Geri Connect and Geri Assess Software that allows users to capture information on embryo development and analyze development using user-defined parameters. The software also allows users to remotely access embryo data. The features added by this additional software do not represent a new intended use, and are seen in other cleared devices of this type.

The design specifications, hardware, firmware, and operation software of the Geri Embryo Incubator as well as Geri Dish are the same as the predicate device (K171736). The only difference in technological characteristics between the subject and predicate devices is addition of the Geri Connect and Geri Assess Software package to the subject device. This difference does not raise different questions of safety and effectiveness as compared to the predicate device. In addition, similar functions are available on other cleared devices of this type.

## VIII. Summary of Non-Clinical Performance Testing

Software verification and validation testing was conducted on the subject device in accordance with the FDA guidance document, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” issued on May 11, 2005.

A rationale was provided regarding the acceptability of the electromagnetic compatibility information from the predicate submission to support the subject device including the Geri Connect and Geri Assess Software.

There have been no changes to the design specifications and hardware of the Geri Embryo Incubator and the Geri Dish since clearance of the predicate device. Therefore, no new performance testing has been carried out on the Geri Embryo Incubator and the Geri Dish.

## 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 devices.