DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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September 28, 2017

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

Re: K170498
Trade/Device Name: Genea Biomedx Gems Oocyte Retrieval Buffer ORB-20, ORB-50
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: August 28, 2017
Received: August 30, 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,

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)*

K170498

Device Name
Genea Biomedx Gems Oocyte Retrieval Buffer ORB-20, ORB-50

Indications for Use *(Describe)*
Gems Oocyte Retrieval Buffer is used in the removal of oocytes from ovarian follicles.

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.

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510(k) Summary
(K170498)

I. General Information on Submitter

Submitter/Address:	Genea Biomedx Pty Ltd Level 2, 321 Kent Street Sydney NSW 2000 Australia
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II. Date Prepared:
September 28, 2017

III. General Information on Devices

Device Name:	Gems Oocyte Retrieval Buffer ORB-20, ORB-50
Common Name:	Embryo Culture Media
Classification Name:	Reproductive Media and Supplements (21 CFR 884.6180)
Product code:	MQL (Media, Reproductive)
Regulatory Class:	II

IV. Predicate Device

Cook Sydney IVF Follicle Flushing Buffer (K002385), manufactured by Cook Ob/Gyn. This predicate device has not been subject to any design related recalls.

V. Device Description

The Gems Oocyte Retrieval Buffer is an assisted reproduction medium used for removal of oocytes from ovarian follicles. It consists of salts, energy substrates, amino acids buffering agents, stabilizers and antibiotics. This device has direct contact with the patients and oocytes.

This product is a single-use device that is aseptically filled into sterilized bottles and has a sterility assurance level (SAL) of 10^{-3}. It is tested for pH, osmolality, embryotoxicity, endotoxin and sterility before lot release and has a shelf-life of 30 weeks.

VI. Indications for Use:

Gems Oocyte Retrieval Buffer is used in the removal of oocytes from ovarian follicles.

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

Device/Predicate Devices	Subject device – Gems Oocyte Retrieval Buffer	Predicate device – Cook IVF Follicle Flushing Buffer (K002385)
Indications for Use	Gems Oocyte Retrieval Buffer is used in the removal of oocytes from ovarian follicles.	Cook IVF follicle flushing buffer is intended for use during in vitro fertilization procedures for follicle flushing and oocyte collection.
pH	7.3-7.5	Similar
Osmolality	280-290 mOsm/kg	Similar
Formulation	Comparable	
The subject and predicate devices have the same intended use – removal of the oocytes from ovarian follicles. The subject and predicate devices also have comparable pH, osmolality, and formulations. In addition, they have comparable specifications for MEA, endotoxin, and sterility. There may be minor differences in technological characteristics between the subject and predicate devices, but 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:

- pH
- Osmolality
- Aseptic Processing Validation testing that met the requirements in ISO 13408-2:2003
- Sterility testing per USP <71>
- Endotoxin testing per USP <85>
- 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.
- Biocompatibility studies, as follows:
  * Cytotoxicity testing per 10993-5:2009
  * Guinea Pig Maximization Sensitization testing per ISO 10993-10:2010
  * Intracutaneous Reactivity testing per ISO 10993-10:2010
- Shelf-life studies (real-time and accelerated) were conducted to ensure that the following product specifications are met at time zero and the end of shelf-life.
  * pH – See tables above
  * Osmolality – See tables above
  * 1-cell MEA – ≥80% developed to the blastocyst stage at 96 hours
  * Endotoxin – <0.4 EU/ml (LAL)
  * Sterility – No microbiological growth

IX. Conclusion

The subject and predicate devices have the same intended use and comparable 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.