May 24, 2017

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

Re: K162409
Trade/Device Name: Gems Vitrification Set and Gems Warming Set
Regulation Number: 21 CFR § 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: April 21, 2017
Received: April 24, 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 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 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
Indications for Use

Gems Vitrification Set is used for the vitrification of human blastocyst stage embryos for Assisted Reproductive Technology (ART) procedures.

Gems Warming Set is used for the warming of human blastocyst stage embryos that have undergone vitrification.

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.
510(k) Summary

I. Submitter Information

Submitter/Address: Genea Biomedx Pty Ltd
Level 2, 321 Kent Street
Sydney
NSW 2000
Australia
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: May 22, 2017

III. General Information on Devices

Device Name: Gems Vitrification Set and Gems Warming Set
Common Name: Vitrification and Warming Media
Classification Name: Reproductive Media and Supplements (21 CFR 884.6180)
Product code: MQL (Media, Reproductive)
Regulatory Class: II

IV. Predicate Devices

Cook Sydney IVF Blastocyst Vitrification Kit and Cook Sydney IVF Blastocyst Warming Kit (K143724)

These predicate devices have not been subject to any design-related recalls.

V. Indications for Use

Gems Vitrification Set is used for the vitrification of human blastocyst stage embryos for Assisted Reproductive Technology (ART) procedures.

Gems Warming Set is used for the warming of human blastocyst stage embryos that have undergone vitrification.

VI. Device Description

The Gems Vitrification Set and Gems Warming Set are intended for the vitrification and warming of human blastocysts as part of human ART procedures.

The Gems Vitrification Set is designed to facilitate dehydration of blastocysts before vitrification via rapid cooling in liquid nitrogen. Dehydration of the blastocysts is achieved by the step-wise use of increasing concentrations of cryoprotectants in the Gems Vitrification Set, which results in water being withdrawn from the cell. The cryoprotectants also protect the blastocysts by reducing the potential for ice crystal formation during the vitrification process.
The Gems Vitrification Set consists of three solutions (Vitsol 1, Vitsol 2, and Vitsol 3). The base formulation for Vitsol 1 and Vitsol 2 is a HEPES-buffered medium containing salts, energy substrates, amino acids, and human serum albumin. Vitsol 1 contains the cryoprotectant ethylene glycol, while Vitsol 2 contains the cryoprotectants ethylene glycol and trehalose. Vitsol 3 consists of dimethyl sulphoxide (DMSO). The Gems Vitrification Set is not provided ready for use as Vitsol 3 must be added to the other vitrification solutions before use. Following DMSO addition to Vitsol 1 and 2, the final vitrification solutions for blastocyst vitrification procedures have the following properties:

- Vitrification Solution 1 (Vitsol 1 + DMSO) – 8% ethylene glycol and 8% DMSO
- Vitrification Solution 2 (Vitsol 2 + DMSO) – 16% ethylene glycol, 16% DMSO, and 0.57M trehalose

The Gems Warming Set consists of three warming solutions (Warmsol 1, Warmsol 2, and Warmsol 3), which are designed to facilitate the re-hydration (warming) of vitrified blastocysts. In the warming process, trehalose in the media manages the inflow of water into blastocysts as concentrations of DMSO and ethylene glycol are reduced during the rehydration process.

All three of the solutions in the Gems Warming Set consist of a HEPES-buffered medium containing salts, energy substrates, amino acids, and human serum albumin, with varying amounts of the cryoprotectant trehalose as described below:

- Warmsol 1 – 1.0 M trehalose
- Warmsol 2 – 0.5 M trehalose
- Warmsol 3 - No trehalose

These media are single-use devices that are aseptically filled into sterilized bottles and have a sterility assurance level (SAL) of 10^{-3}. The products are tested for pH, osmolality, embryotoxicity, endotoxin, and sterility before lot release.

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

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Subject Device – Gems Vitrification Set and Gems Warming Set (K162409)</th>
<th>Predicate Device – COOK Sydney IVF Blastocyst Vitrification Kit and COOK Sydney IVF Blastocyst Warming Kit (K143724)</th>
<th>Comparison</th>
</tr>
</thead>
</table>
| Indication for Use | Gems Vitrification Set is used for the vitrification of human blastocyst stage embryos for Assisted Reproductive Technology (ART) procedures.  
Gems Warming Set is used for the warming of human blastocyst stage embryos that have undergone vitrification. | Blastocyst Vitrification Kit is intended for the vitrification of human blastocysts for assisted reproduction technologies (ART). This kit is designed for use with Blastocyst Warming Kit (K-SIBW-5000).  
Blastocyst Warming Kit is intended for the warming of human blastocysts that have undergone vitrification using COOK Sydney IVF Vitrification Kit (K-SIBV-5000) for ART procedures. | Same Intended Use – vitrification and warming of human blastocyst stage embryos. |
<table>
<thead>
<tr>
<th>Parameter</th>
<th>Subject Device – Gems Vitrification Set and Gems Warming Set (K162409)</th>
<th>Predicate Device – COOK Sydney IVF Blastocyst Vitrification Kit and COOK Sydney IVF Blastocyst Warming Kit (K143724)</th>
<th>Comparison</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation</td>
<td>HEPES buffered physiologic media containing ethylene glycol, DMSO, trehalose, and human serum albumin in addition to normal physiological salts. DMSO provided in a separate vial and must be added to vitrification media before use.</td>
<td>HEPES buffered physiologic media containing ethylene glycol, DMSO, trehalose, human Serum albumin and gentamicin in addition to normal physiological salts. DMSO provided in a separate vial and must be added to vitrification media before use.</td>
<td>Different - Formulas for the vitrification and Warming Vitrification Solutions are similar, consisting of the same components with the exception of gentamicin (not in subject device). Some differences in concentrations. Differences noted above do not raise different questions of safety and effectiveness (S&amp;E).</td>
</tr>
<tr>
<td>pH</td>
<td>7.3-7.5</td>
<td>7.3-7.5</td>
<td>Same</td>
</tr>
<tr>
<td>MEA</td>
<td>1-Cell MEA: ≥80% developed to blastocysts at 96h</td>
<td>2-Cell MEA: ≥80% blastocyst formation at 72h</td>
<td>Similar</td>
</tr>
<tr>
<td>Endotoxin</td>
<td>Vitsol 1-2, Warmsol 1-3 &lt; 0.40 EU/mL DMSO &lt;0.05 EU/ml</td>
<td>&lt; 0.40 EU/mL</td>
<td>Similar</td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>Aseptic Filtration SAL 10⁻³</td>
<td>Aseptic Filtration</td>
<td>Same</td>
</tr>
<tr>
<td>Shelf-Life</td>
<td>20 weeks</td>
<td>20 weeks</td>
<td>Same</td>
</tr>
</tbody>
</table>

As noted in the table above, the devices have the same intended use and are technologically comparable. Differences in technological characteristics noted above do not raise different questions of safety or 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 sequentially to subject devices in the Vitrification and Warming Sets followed by culture at 37°C in an atmosphere containing 5% CO₂. The percent of embryos developed to the expanded blastocyst stage at 96 hours were assessed in comparison with the control group.
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 – 7.3-7.5
* Osmolality – See technological comparison table above for specifications
* 1-cell MEA – ≥80% developed to the blastocyst stage at 96 hours
* Endotoxin – <0.4 EU/ml (LAL) for Vitsol 1-2, and Warmsol 1-3
* Sterility – No microbiological growth

IX. Conclusions

The results of the performance testing conducted on the subject device demonstrate that it is as safe and effective as the predicate device and supports substantial equivalence.