



Food and Drug Administration  
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February 29, 2016

Origio A/S  
Tove Kjaer  
Director Corporate Regulatory Affairs  
Knardrupvej 2  
2760 Måløv  
Denmark

Re: K152932  
Trade/Device Name: BlastGen™  
Regulation Number: 21 CFR 884.6180  
Regulation Name: Reproductive media and supplements  
Regulatory Class: Class II  
Product Code: MQL  
Dated: January 29, 2016  
Received: February 8, 2016

Dear Tove Kjaer,

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 yours,

  
**Herbert P. Lerner -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

510(k) Number (if known)

K152932

Device Name

BlastGen™

Indications for Use (Describe)

BlastGen™ is for the culture of embryos from the 4-8 cell stage through to the blastocyst stage.

BlastGen™ can also be used for embryo transfer.

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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**K152932 - BlastGen™****510(k) SUMMARY**

**Submitted by:** ORIGIO a/s  
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Denmark

**Contact Person:** Tove Kjær  
Director Corporate Regulatory Affairs  
ORIGIO a/s

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**Date Prepared:** February 24, 2016

**Device Identification**

Trade name: BlastGen™ (Cat. No. 1205)

Common name: BlastGen™ (Cat. No. 1205)

Classification name: Reproductive media and supplements (21 CFR 884.6180, Product Code MQL)

**Predicate Devices:** ORIGIO® Sequential Blast™ (Cat. No. 8305) (K133387)

**Device Description:**

BlastGen™ is based on ORIGIO® Sequential Blast™ (K133387) with the supplement of Leukine (Sargramostim) granulocyte macrophage colony-stimulating factor (GM-CSF).

BlastGen™ is a colorless, non-viscous solution contained in 3mL transparent glass bottles with white polypropylene caps, available in a single piece card board box, individually labeled and with instruction for use provided as a package insert. BlastGen™ is a ready to use by professionals for assisted reproduction.

BlastGen™ is quality control tested before release for pH, sterility, Mouse Embryo Assay, endotoxin, osmolality, GM-CSF concentration (by ELISA), GM-CSF potency (TF-1 cell assay) and human serum albumin (HSA) concentration (by ELISA).

**Indication for Use:**

BlastGen™ is for the culture of embryos from the 4-8 cell stage through to the blastocyst stage. BlastGen™ can also be used for embryo transfer.

**Performance and Safety Data:****Biocompatibility**

BlastGen™ is categorized as a medium in direct contact with embryos from the 4-8 cell stage to blastocyst stage. Since BlastGen™ can also be used for embryo transfer, it is also in contact with the uterus (patient). In accordance with ISO 10993-1:2009, the

cytotoxicity, sensitization and irritation tests have been conducted and the results demonstrated that BlastGen™ was safe.

### **Sterilization Validation**

BlastGen™ is manufactured by aseptically filtration that was validated in accordance with EN/ISO 13408-2:2011. This product has a sterility assurance level (SAL) of  $10^{-3}$ .

### **Shelf-Life**

The BlastGen™ has been evaluated for pH, osmolality, sterility, mouse embryo assay, endotoxin, GM-CSF concentration, GM-CSF potency and HSA concentration in shelf-life testing. Under recommended storage conditions, BlastGen™ has 26-week shelf-life in unopened bottle and 7-day stability after the bottle has been opened.

### **Clinical Evidence**

A prospective randomized sibling zygote pilot study ( $n=371$  zygotes) of GM-CSF-containing media (EmbryoGen/BlastGen) for culturing embryos to the blastocyst stage showed a trend towards higher blastocyst rate in the EmbryoGen/BlastGen group compared to G1/G2 although these differences did not reach statistical significance. A trend towards higher pregnancy and ongoing implantation rates were also observed for EmbryoGen/BlastGen (Nakajyo et al., 2016).

The addition of GM-CSF increased the proportion of embryos that developed to the blastocyst stage from 30 to 76%. The developmental competence of these blastocysts (hatching and attachment to extracellular matrix-coated culture dishes), was also improved by GM-CSF (Sjöblom et al., 1999).

Blastocysts cultured in 2 ng/ml GM-CSF contained 50% fewer apoptotic nuclei and 30% more viable inner cell mass cells, compared to the control (Sjöblom et al., 2002)

### **Conclusion:**

BlastGen™ and predicate device have the same indications and comparable technological characteristics. Based on non-clinical and clinical performance data, BlastGen™ is substantially equivalent to the predicate device in terms of safety and effectiveness.