DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 28, 2016

KITAZATO BioPharma Co., Ltd.
% Diane Sudduth
Senior Regulatory Consultant
Emergo Global Consulting, LLC
816 Congress Avenue, Suite 1400
Austin, TX 78701

Re: K160863
Trade/Device Name: PBS(-), Phosphate Buffered Saline
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: June 23, 2016
Received: June 27, 2016

Dear Diane Sudduth:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160863

Device Name
PBS(-), Phosphate Buffered Saline

Indications for Use *(Describe)*
PBS(-), Phosphate Buffered Saline is intended for use in assisted reproductive procedures that involve the manipulation of gametes and embryos. These procedures include oocyte retrieval from ex vivo ovarian tissues, short term oocyte maintenance, and handling of fertilized embryos prior to 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary
(K160863)

1. Submission Sponsor

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3. Date Prepared

07/27/2016

4. Device Identification

Trade/Proprietary Name:	PBS(-), Phosphate Buffered Saline
Common/Usual Name:	Phosphate Buffered Saline
Classification Name:	Reproductive media and supplements
Regulation Number:	21 CFR 884.6180
Product Code:	MQL, Reproductive media and supplements
Device Class:	Class II
Classification Panel:	Obstetrics/Gynecology

5. Legally Marketed Predicate Device(s)

Irvine Scientific, PBS 1X (K991342)

6. Device Description

Phosphate Buffered Saline [PBS(-)] is a colorless, odorless isotonic buffered solution with a pH of 7.20-7.60.

PBS(-) composition:

- Sodium Chloride
- Potassium Chloride
- Monopotassium phosphate
- Di-sodium Hydrogen Phosphate Anhydrous

PBS(-) will be available in volumes of 100mL and 500mL. Packaging for PBS(-) consist of a PETG (Polyethylene Terephtalate Glycol-modified) bottle and HDPE (High Density Polyethylene) cap. PBS(-) has a six-month shelf-life.

7. Indication for Use

PBS(-), Phosphate Buffered Saline is intended for use in assisted reproductive procedures that involve the manipulation of gametes and embryos. These procedures include oocyte retrieval from ex vivo ovarian tissues, short term oocyte maintenance, and handling of fertilized embryos prior to embryo transfer.

8. Substantial Equivalence Discussion

Differences exist in the indications for use between the predicate and subject devices. Specifically, the predicate device is indicated for additional ART procedures (embryo transfer). This difference represents a narrower indication for use for the subject device and does not represent a new intended use as both devices are used for manipulation of gametes and embryos during ART procedures.

The subject and predicate devices have the same fundamental technological characteristics. Both are buffered solutions with similar pH and osmolality ranges meeting the physiological requirements of gametes and embryos. Although there are differences in the formulations of these devices, the differences do not represent a new technology as they do not raise different questions of safety and effectiveness.

9. Performance Data

Non-clinical performance testing demonstrated that all product specifications were met as follows:

ASSAY	SPECIFICATIONS
Color	Clear, Particle Free
pH	7.20-7.60
Osmolality	279-295mOsm/kg
Endotoxin	<0.25 EU/mL
Sterility	No Microbial Growth
1-cell MEA	≥80% developed to blastocyst at 96 hrs

Shelf-life testing demonstrated that PBS(-) maintained all specifications at the end of the six-month shelf-life period.

10. Conclusion

The subject and predicate devices have the same intended use and fundamental technological characteristics. The differences in technological characteristics do not raise different types of questions and can be assessed by bench performance testing. Performance data demonstrated that the subject device is substantially equivalent to the predicate device in terms of safety and effectiveness.