DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 27, 2015

William A. Cook Australia Pty, Ltd..
Gordana Pozvek
Senior Regulatory Affairs Specialist
95 Brandl Street
Brisbane Technology Park, Eight Mile Plains
Brisbane QLD 4113, Austrailia

Re: K143724
Trade/Device Name: COOK Sydney IVF Blastocyst Vitrification Kit, COOK Sydney IVF Blastocyst Warming Kit
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: July 28, 2015
Received: July 31, 2015

Dear Gordana Pozvek,

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,

Joyce M. Whang -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)*
K143724

Device Name
COOK Sydney IVF Blastocyst Vitrification Kit

Indications for Use *(Describe)*
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).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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)*
K143724

Device Name
COOK Sydney IVF Blastocyst Warming Kit

Indications for Use *(Describe)*
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.

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)

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510(k) Summary

SUBMITTED BY:

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Date Prepared: August 26, 2015

DEVICE IDENTIFICATION:

Trade Name:	COOK Sydney IVF Blastocyst Vitrification Kit (K-SIBV-5000) COOK Sydney IVF Blastocyst Warming Kit (K-SIBW-5000)
Common Name:	Blastocyst Vitrification & Warming Kits
Regulation No:	21 CFR 884.6180, Reproductive Media & Supplements
Regulatory Class:	II
Product Code:	MQL - Media, Reproductive

PREDICATE DEVICE:

COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit (product codes: K-SIBV-5000, K-SIBW-5000) **(K082363).**

DEVICE DESCRIPTION:

COOK Sydney IVF Blastocyst Vitrification and Warming Kits are intended for the vitrification and warming of human blastocysts as part of human ART procedures. The COOK Sydney IVF Blastocyst Vitrification and Warming Kits provide users with the ability to cryopreserve supernumerary embryos created during the *in vitro* fertilization procedure and then to re-warm them for use at a future point in time.

The COOK Sydney IVF Blastocyst Vitrification Kit (K-SIBV-5000) consists of a series of 2-[4-(2-hydroxyethyl)piperazin1-yl] ethanesulfonic acid (HEPES)–buffered, physiological solutions containing increasing concentrations of functional cryoprotectants to which the

embryo is sequentially exposed during cryopreservation. The first three solutions in the kit are all based upon the same formulation (known as "Cryobase buffer"), which is a 10 mM HEPES buffered media containing 20 mg/mL Human Serum Albumin (HSA) and 0.01 mg/mL Gentamicin. The fourth solution in the kit is dimethyl sulfoxide (DMSO) and does not contain HSA or Gentamicin. The DMSO is provided for the practitioner to add to Solution 2 and Solution 3 of the vitrification kit, as described in the Instructions for Use. .

COOK Sydney IVF Blastocyst Warming Kit (K-SIBW-5000) consists of three solutions which are used sequentially throughout the warming process. The three media in the kit are all based upon the same formulation of Cryobase buffer, a 10 mM HEPES buffered media containing 20 mg/mL HSA and 0.01 mg/mL Gentamicin.

The COOK Sydney IVF Blastocyst Vitrification and Warming Kits are single use, sterile (aseptic filtration) devices.

These solutions contact the blastocyst during the vitrification and re-warming process. The solutions are removed by washing prior to embryo transfer back to the patient and are therefore non-patient contacting.

INDICATIONS FOR USE:

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.

The only differences in the intended use listed above and that of the predicate device are:

- An update to current indications for use for the Blastocyst Vitrification Kit, replacing "assisted reproduction **procedures** (ART)" with the proper acronym, "assisted reproduction **technologies** (ART)".

- In the indications for use for the Blastocyst Warming Kit, **"warming** of human blastocysts" replaces **"recovery** of human blastocysts," which is used in the predicate device. This is an update to clarify the purpose of the device. There is no change to the clinical use of the device.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

The COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit and the predicate device **(K082363)** have the same fundamental technology and many of the same technological characteristics including the following:

- Same chemical formulation
- Same performance specifications:
  - pH 7.3 - 7.5
  - Osmolality 285 - 295 mOsm/kg (Cryobase Solution)
  - Endotoxin < 0.40 EU/mL
  - 2-cell MEA ≥ 80% of control at 72 hours
- Same method of manufacturing process - aseptic filtration
- Same packaging – borosilicate type 1 vials with FluroTec stopper and tamper evident seals

The modification that was made to the predicate device was a change in shelf-life from 8 weeks (for predicate device) to 20 weeks.

A full comparison is provided below in Table 1.

Table 1: Comparison of COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit with predicate device

Device Name	**Predicate Device (K082363):**	**Proposed Device:**	**Comparison**
	COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit	**COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit**	
Regulation Number	21 CFR 884.6180	21 CFR 884.6180	Same
Product Code	MQL	MQL	Same
Classification	Reproductive Media and Supplements	Reproductive Media and Supplements	Same
Indications for Use	Blastocyst Vitrification Kit is intended for the vitrification of human blastocysts for assisted reproduction procedures (ART). This kit is designed for use with Blastocyst Warming Kit (K-SIBW-5000).	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).	Clerical update – replaced "assisted reproduction procedures (ART)" with its proper acronym "assisted reproduction technologies (ART)".
	Blastocyst Warming Kit is intended for the recovery of human blastocysts that have undergone vitrification using COOK Sydney IVF Vitrification Kit (K-SIBV-5000) for ART procedures.	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.	Current Intended use has the wording "warming" instead of "recovery". This is an update to clarify the purpose of the device, no change to clinical use of the device.

Device Name	Predicate Device (K082363):	Proposed Device:	Comparison
	COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit	**COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit**	
Principal of Operation	Provides users with the ability to cryopreserve supernumerary embryos created during the in vitro fertilization procedure and then to re-warm them for use at a future point in time.	Provides users with the ability to cryopreserve supernumerary embryos created during the in vitro fertilization procedure and then to re-warm them for use at a future point in time.	Same
Formulation	HEPES buffered physiologic media containing ethylene glycol, DMSO, trehalose, Human Serum Albumin & Gentamicin in addition to the normal physiological salts.	HEPES buffered physiologic media containing ethylene glycol, DMSO, trehalose, Human Serum Albumin & Gentamicin in addition to the normal physiological salts.	Same
Packaging	Borosilicate type 1 vials with Fluorotec coated butyl rubber stoppers and tamper-evident aluminium seals. Sealed vials are packaged into a cardboard outer box	Borosilicate type 1 vials with Fluorotec coated butyl rubber stoppers and tamper-evident aluminium seals. Sealed vials are packaged into a cardboard outer box	Same
Shelf-life	8 weeks at 2 – 8ºC	20 weeks at 2 - 8°C	The 8-week shelf life for IVF Media was extended to 20 weeks from date of manufacture when stored at 2 - 8°C. Stability testing was carried out on the Cook IVF Media suite to verify that the properties of the device are maintained during the entire shelf-life of 20 weeks.
Product Specification			
pH	7.30 - 7.50	7.30 - 7.50	Same
Osmolality (mOsm/kg)	K-SIBV-SOL1: 285 – 295 K-SIBV-SOL2: N/A* K-SIBV-SOL3: N/A*	K-SIBV-SOL1: 285 – 295 K-SIBV-SOL2: N/A* K-SIBV-SOL3: N/A*	Same

Device Name	Predicate Device (K082363):	Proposed Device:	Comparison
	COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit	**COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit**	
	K-SIBW-SOL1: 665 - 675 K-SIBW-SOL2: 505 - 515 K-SIBW-SOL3: 285 - 295	K-SIBW-SOL1: 657 – 683 K-SIBW-SOL2: 500 - 520 K-SIBW-SOL3: 285 - 295	A slight change was made to the osmolality specifications for Blastocyst Warming Kit Solutions 1 & 2. The modification was introduced to improve manufacturability and to ensure consistency with the other solutions in the kits. The modified osmolality specifications were not related to any changes in the device and do not raise any safety concerns.
2-cell MEA (72 hrs)	≥ 80% of control	≥ 80% of control	Same
Endotoxin	< 0.40 EU/mL	< 0.40 EU/mL	Same
Bioburden	In-process pre-filtration specification: <100 CFU/mL Release Specification: < 1 CFU	In-process pre-filtration specification: <100 CFU/mL Release Specification: Not performed	In-process pre-filtration bioburden specification: Same Bioburden Release Specification: Sterility was implemented as a release test, and therefore Bioburden testing as a release test was redundant.
Sterility (USP/EP/JP)	Not performed	No Growth	The device is supplied sterile (aseptically filtered), therefore testing to the JP/EP/USP Pharmacopeia was implemented. Sterility testing makes bioburden testing redundant.
Manufacturing process	Aseptic filtration	Aseptic filtration	Same
HSA Assay	Not performed	10.00 – 40.00 mg/mL	Additional release test to assay Human Serum Albumin, included as an additional control to verify quality of the batch.

* The osmometer measures osmolality by freezing samples and correlating the freeze point to the osmolality. The high concentration of cryoprotectants in K-SIBV-SOL2 and K-SIBV-SOL3 prevents freezing of the solutions, therefore it is not possible to measure the osmolality of these two solutions.

PERFORMANCE DATA:

The product specifications for the COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit and the predicate device are the same regarding sterility, endotoxin, pH, and the MEA.

Stability & Shelf Life

The shelf-life of COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit has been validated in stability studies to 20 weeks at 2 - 8^{o}C. Stability tests included pH, osmolality, endotoxin, MEA, sterility and the concentrations of amino acids (proline and lysine), pyruvate and ammonia.

CONCLUSION:

The results of the testing provide reasonable assurance that the COOK Sydney IVF Blastocyst Vitrification Kit & COOK Sydney IVF Blastocyst Warming Kit is as safe and effective as the predicate device and supports a determination of substantial equivalence.