January 12, 2018

Willian A. Cook Australia Pty. Ltd.
Gordana Pozvek, Ph.D.
Senior Regulatory Affairs Specialist
95 Brandl Street
Eight Mile Plains, Queensland 4113
Australia

Re: K171625
Trade/Device Name: Single Lumen Ovum Aspiration Needles
Regulation Number: 21 CFR§ 884.6100
Regulation Name: Assisted Reproduction Needles
Regulatory Class: II
Product Code: MQE
Dated: December 12, 2017
Received: December 15, 2017

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*

K171625

Device Name

Single Lumen Ovum Aspiration Needles

Indications for Use *(Describe)*

The Single Lumen Ovum Aspiration Needles are used for laparoscopic or ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles for patients undergoing Assisted Reproductive 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)

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

WILLIAM A. COOK AUSTRALIA PTY. LTD.
95 BRANDL STREET
BRISBANE TECHNOLOGY PARK, EIGHT MILE PLAINS
BRISBANE, QLD 4113, AUSTRALIA
PHONE: 1800.777.222 FAX: +61.7.3841.1288
WWW.COOKMEDICAL.COM
ABN 79 005 526 723

510(k) Summary – K171625

SUBMITTED BY:

William A. Cook Australia Pty Ltd
95 Brandl Street
Eight Mile Plains QLD 4113
Australia

Contact Person: Gordana Pozvek Ph.D.
Tel: +61 (7) 3841 1188
Fax: +61 (7) 3841 3905
E-mail: Gordana.Pozvek@CookMedical.com

Date Prepared: January 11, 2018

DEVICE IDENTIFICATION:

Trade Name:	Single Lumen Ovum Aspiration Needles
Common Name:	Oocyte Retrieval Needles
Regulation No:	21 CFR 884.6100, Assisted Reproduction Needles
Regulatory Class:	II
Product Code:	MQE - Needle, Assisted Reproduction

PREDICATE DEVICE:

Ovum Pick-Up Aspiration Needles (**K983593)**

The predicate device has not been subject to a design-related recall.

DEVICE DESCRIPTION:

Single Lumen Ovum Aspiration Needles consist of a stainless-steel needle with a manipulating handle which may be connected to a fluorinated ethylene-propylene (FEP) or polytetrafluorethylene (PTFE) tube, which in turn is connected to a Silicone stopper (bung). The stopper has a Luer lock fitting directly to the stopper or connected to a length of tube to allow connection to a vacuum pump which provides aspiration suction. The stopper is placed in a 14mL test tube which acts as a collection reservoir. Needles are available in 16 to 21 gauge sizes and lengths from 25 to 35 cm. Needles have an echogenic tip that enhances the visualization of the needle tip under ultrasound.

The Single Lumen Ovum Aspiration Needles are sterile and single-use devices.

The following needle series are included in this 510(k):

Product codes	Needle gauge	Needle length (cm)	Aspiration Line (cm)	Vacuum Line (cm)	Flushing Line (cm)	Bevel Type
K-OPAA-series	17, 18, 20	35	n/a	n/a	n/a	B
K-DOPU-series	17	28 or 35	60 or 90	n/a	n/a	B
K-OPS-series	16, 17, 19, 20, or 21	28, 30, 33, or 35	60 or 90	n/a	n/a	A or B
K-OSN-series	16 or 17	25, 30, 33, or 35	60 or 90	50	n/a	A or B
K-IOPS-series	20	35	60	50	n/a	A
K-UCI-series	16 or 17	30 or 35	60	n/a	60	A

INDICATIONS FOR USE:

The Single Lumen Ovum Aspiration Needles are used for laparoscopic or ultrasound guided transvaginal aspiration and flushing of oocytes from ovarian follicles for patients undergoing Assisted Reproductive procedures.

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Single Lumen Ovum Aspiration Needles ha*ve* similar Indications for Use as the predicate device (K983593). The intended use of the subject device is the same as the predicate device.

The Single Lumen Ovum Aspiration Needles are a modification of the Ovum Pick-up Aspiration Needle*s* (K983593). The modifications are:

- The indications for use statement has been modified from the predicate device to include transvaginal ultrasound and laparoscopic approaches, both of which were specifically stated within cleared labeling for the legally marketed device. This modification to the Indication for Use statement does not impact safety and effectiveness of the device.

- Addition of a 21-gauge variant to the K-OPS Series needles. This modification provides a smaller gauge needle option. The 21-gauge variant has a 4 Fr aspiration tubing.

- Addition of a 17 gauge, 30 cm guide needle. This modification provides a guide needle size suitable for the 20-gauge K-IOPS variant.

- The aspiration and flushing tubing has changed from Tetrafluoroethylene (NRT [TFE]) to Fluorinated Ethylene Propylene (NRT-FEP) and Polytetrafluoroethylene (NRT-PTFE).

The modifications listed above do not raise different questions of safety and effectiveness as compared to the predicate device.

PERFORMANCE DATA:

To support the modifications to the subject device, the following design verification and validation activities were performed and summarized:

- Biocompatibility per ISO 10993-1:2009
  - Cytotoxicity (ISO 10993-5:2009)
  - Sensitization (ISO 10993-10:2010)
  - Irritation (ISO 10993-10:2010)
- Mouse Embryo Assay – Two cell mouse embryos were exposed to device extracts and cultured at 37ºC in an atmosphere containing 5% CO_2. The percent of embryos developed to the expanded blastocysts stage within 72 hours were assessed in comparison with the control group. The acceptance criteria for this test is ≥80% development to blastocyst at 72 hours.
- Endotoxin testing per USP <85> (≤ 20 EU/Device)
- Mechanical performance testing
  - Negative pressure leak test
  - Tensile strength of the tubing to cannula
  - Tensile strength of the tubing to bung
  - Tensile strength of joint between cannula and handle
  - Tensile strength of 4 Fr tubing
  - Tensile strength of the joint between guide needle cannula and hub
  - Needle stiffness
- Stability testing
  - Negative pressure leak test after three years of aging
  - Tensile testing of joint between handle and needle cannula after three years of aging
  - Torque testing of joint between guide needle cannula and hub after three years of aging

CONCLUSION:

The results of the testing provided demonstrated that the Single Lumen Ovum Aspiration Needle is as safe and effective as the predicate device and supports a determination of substantial equivalence.