December 15, 2017

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

Re: K171611
Trade/Device Name: Double Lumen Ovum Aspiration Needles
Regulation Number: 21 CFR 884.6100
Regulation Name: Assisted Reproduction Needles
Regulatory Class: Class II
Product Code: MQE
Dated: November 13, 2017
Received: November 17, 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,

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)*

K171611

Device Name

Double Lumen Ovum Aspiration Needles

Indications for Use *(Describe)*

The Double 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.

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 – K171611

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: December 14, 2017

DEVICE IDENTIFICATION:

Trade Name: Double 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)**,** January 21, 1999.

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

DEVICE DESCRIPTION:

Double Lumen Ovum Pick-up Needles consist of a double lumen stainless steel needle with a manipulating handle. The manipulating handle has two ports: the central port through which oocytes are aspirated via the central lumen, and a secondary side port to allow flushing of follicles via a secondary lumen. The needle is intended to be used to aspirate oocytes from follicles of human ovaries via a laparoscopic or ultrasound guided transvaginal path.

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

The Double Lumen Ovum Aspiration Needles are available in 16 or 17 gauge sizes and three lengths: 30, 33 and 35 cm. The needles are provided with an aspiration tube of 75 cm length and a vacuum tube with a length of 70 or 100 cm.

INDICATIONS FOR USE:

The Double 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:

Double Lumen Ovum Aspiration Needles have similar Indications for Use as the predicate device (K983593). The intended use of the subject device is the same as the predicate device.

The Double Lumen Ovum Aspiration Needle is a modification of the Ovum Pick-up Aspiration Needle (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.

- The aspiration and flushing tubing, a fluid contacting material, has changed from Tetrafluoroethylene (NRT [TFE]) to Fluorinated Ethylene Propylene (NRT-FEP).

- Minor changes in the range of dimensions for the needle gauge, inner cannula diameter, needle length, and aspiration tubing length and diameter.

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 37°C 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.

- Endotoxin testing per USP <85>
- Mechanical performance testing
    - Negative pressure leak test
    - Tensile strength of the tubing to cannula
    - Tensile strength of the tubing to bung
- Stability testing
    - Negative pressure leak test after three years of real time aging

CONCLUSION:

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