May 18, 2018

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

Re: K173431
Trade/Device Name: Towako Transmyometrial Embryo Transfer Set
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: Class II
Product Code: MQF
Dated: April 17, 2018
Received: April 20, 2018

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)*

K173431

Device Name
Towako Transmyometrial Embryo Transfer Set

Indications for Use *(Describe)*
The Towako Transmyometrial Embryo Transfer Set is indicated for transferring IVF embryo(s) into the endometrial cavity through the myometrium 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.

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510(k) Summary - K173431

SUBMITTED BY:

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Date Prepared: May 17, 2018

DEVICE IDENTIFICATION:

Trade Name:	Towako Transmyometrial Embryo Transfer Set
Common Name:	Embryo Transfer Catheter
Regulation No:	21 CFR 884.6110, Assisted Reproduction Catheters
Product Code:	MQF - Catheter, Assisted Reproduction
Regulatory Class:	II

PREDICATE DEVICE:

Transmyometrial Embryo Transfer Set (K983595)

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

DEVICE DESCRIPTION:

The Towako Transmyometrial Embryo Transfer Set is comprised of an echo tipped stainless steel 19 Gauge needle, matching stainless steel stylet and a 2 Fr polyethylene transfer catheter. The stylet fits into the needle with both bevels flush, and is inserted with the stylet *in-situ* to prevent blockage of the needle lumen and provide stiffness to the needle during insertion. When the needle is positioned correctly, the stylet is removed and the transfer catheter with the embryos loaded is inserted to allow embryo transfer. The device is used when difficulty is experienced in transferring embryos into the uterine cavity using a standard trans-cervical route.

The Towako Transmyometrial Embryo Transfer Set is a sterile and single-use device.

INDICATIONS FOR USE:

The Towako Transmyometrial Embryo Transfer Set is indicated for transferring IVF embryo(s) into the endometrial cavity through the myometrium for patients undergoing Assisted Reproductive Procedures.

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

The Towako Transmyometrial Embryo Transfer Set is a modification of the Transmyometrial Embryo Transfer Set (K983595).

Intended Use

The indication for use statements of the subject and predicate devices are shown below:

Subject Device K173431	Predicate Device K983595
The Towako Transmyometrial Embryo Transfer Set is indicated for transferring IVF embryo(s) into the endometrial cavity through the myometrium for patients undergoing Assisted Reproductive Procedures.	The Transmyometrial Embryo Transfer Sets are used for transferring IVF embryo(s) into the endometrial cavity through the myometrium. These devices are sterile and intended for one-time use. The Transmyometrial Embryo Transfer Set should not be used on a patient with an active vaginal or intrauterine infection, a sexually transmitted disease, a recent uterine perforation, cervical stenosis or other cervical abnormalities which would preclude embryo transfer, a recent caesarean section, a recent pregnancy (or is currently pregnant), or if a patient currently has an intrauterine device.

The indications for use statement has been modified from the predicate device to include wording that describes the patient population, remove descriptive information, and remove contraindication information. These modifications to the Indication for Use statement are for clarification only and do not impact the intended use or safety and effectiveness of the subject device.

Technological Characteristics

Differences between the subject and predicate devices are as follows:

- Replacement of the 17 G guide needle with 19 G stylet. The guide needle in the predicate device provides stiffness for insertion of the needle into the myometrium. The guide needle has been replaced with a stylet which also provides stiffness to the needle during insertion. In addition, the stylet also limits the introduction of foreign material into the needle.

- The Transfer Catheter tubing, a fluid contacting material, has changed from Tetrafluoroethylene (NRT [TFE]) to Polyethylene.

- Minor dimensional changes to the transfer catheter

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:

- Biocompatibility per ISO 10993-1:2009
  - Cytotoxicity (ISO 10993-5:2009)
  - Sensitization (ISO 10993-10:2010)
  - Irritation (ISO 10993-10:2010)
- Mouse Embryo Assay (MEA) – 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
  - Tensile strength between stylet wire and hub
  - Tensile strength of catheter shaft
  - Tensile strength between catheter shaft and hub
  - Positive pressure leak test of transfer catheter
- Stability testing
  - Tensile strength between stylet wire and hub after three years of aging
  - Tensile strength between transfer catheter and hub after three years of aging
  - Tensile strength of transfer catheter shaft after three years of aging
  - Positive pressure leak test of transfer catheter after three years of aging
  - MEA testing after three years of aging

CONCLUSION:

The results of the testing provided demonstrated that the Towako Transmyometrial Embryo Transfer Set is as safe and effective as the predicate device and supports a determination of substantial equivalence.