DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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June 13, 2017

William A. Cook Australia Pty Ltd
Gordana Pozvek, Ph.D.
Senior Regulatory Affairs Specialist
95 Brandl Street
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Australia

Re: K160753
Trade/Device Name: COOK Vacuum Pump
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulatory Class: II
Product Code: MQG
Dated: May 10, 2017
Received: May 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.

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,

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)*
K160753

Device Name
COOK Vacuum Pump

Indications for Use *(Describe)*
The COOK Vacuum Pump is intended for the aspiration of eggs (ova), during assisted reproduction procedures using low flow, intermittent vacuum.

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

SUBMITTED BY:

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Date Prepared: June 11, 2017

DEVICE IDENTIFICATION:

Trade Name:	COOK Vacuum Pump
Common Name:	Vacuum Pump
Classification Name:	Assisted Reproduction Accessories (21 CFR 884.6120)
Product Code:	MQG (Accessory, Assisted Reproduction)
Regulatory Class:	II

PREDICATE DEVICE:

COOK Ultra Quiet Vacuum Pump & Regulator (K992070), manufactured by COOK Urological, Inc. This predicate device has not been subject to any design related recalls.

DEVICE DESCRIPTION:

The COOK Vacuum Pump (K-MAR-5200) is an electrically-powered, vacuum pump that is used for the collection of ova (eggs) from ovarian follicles for use in *in vitro* fertilization (IVF) procedures. The COOK Vacuum Pump provides vacuum levels ranging from -10 mmHg to -500 mmHg. . It is supplied non-sterile.

The disposable Vacuum Line with Hydrophobic Filter (K-DVLF-240) is an accessory to the COOK Vacuum Pump and is used to connect the vacuum pump to an ovum aspiration needle. This component has been designed and tested to withstand the maximum vacuum

pressures associated with the COOK Vacuum Pump. The Vacuum Line with Hydrophobic Filter (K-DVLF-240) is provided sterile (ethylene oxide sterilization) for single use only, and has a shelf-life of three years.

INDICATIONS FOR USE:

The COOK Vacuum Pump is intended for the aspiration of eggs (ova), during assisted reproduction procedures using low flow, intermittent vacuum.

COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS OF SUBJECT AND PREDICATE DEVICES:

Device/Predicate Devices	**SUBJECT DEVICE:** **COOK Vacuum Pump**	**PREDICATE DEVICE:** **COOK Ultra Quiet Vacuum Pump & Regulator (K992070)**
Indications for Use	Same as predicate device	The COOK Ultra Quiet Vacuum Pump & Regulator is intended for the aspiration of eggs (ova), during assisted reproduction procedures using low flow, intermittent vacuum.
Fundamental technology	Same as predicate device	A single diaphragm pump is attached to a motor. The suctioned air is collected in the pressure reservoir. A pressure gauge is connected to the pressure reservoir and the pressure is displayed. The aspiration pressure sensor detects the set aspiration pressure and the aspiration pressure during the boost operation. A motor controlled by an aspiration pressure control circuit adjusts the detected pressure and maintains the set pressure.
Vacuum range	-10 mmHg to -500 mmHg	-30 mmHg to -300 mmHg
Recommended flow rate	Same as predicate device	20-25 mL/min
Vacuum range accuracy	Same as predicate device	± 5 mmHg
Boost function	The vacuum can be boosted to -500 mmHg from any setting during operation	No
Foot pedal	Same as predicate device	Yes
Controller	Microprocessor electronic control	Analogue electronic control
Software	Yes	No

Device/Predicate Devices	SUBJECT DEVICE: COOK Vacuum Pump	PREDICATE DEVICE: COOK Ultra Quiet Vacuum Pump & Regulator (K992070)
The subject and predicate devices have the same indications for use and intended use. They also use the same fundamental technology to create a vacuum and have the same recommended flow rate for ovum (egg) aspiration procedures. The subject device has a vacuum range from -10 mmHg to -500 mmHg, whereas the predicate device has a vacuum rage from -10 mmHg to -300 mmHg. The higher vacuum pressure provided by the subject device (from -300 mmHg to -500 mmHg) is only intended to be applied during use of the "boost" function to clear blockages in the aspiration line or aspiration needle, when the needle is outside the patient. Therefore, the difference in vacuum range does not raise different questions of safety or effectiveness. Unlike the predicate device that used an analogue electronic control, control of the subject device is done using a microprocessor and software. This difference does not raise different types of safety and effectiveness questions.		

SUMMARY OF NON-CLINICAL PERFORMANCE TESTING:

The following studies have been performed to support substantial equivalence to the predicate devices:

- Electrical Safety Testing per IEC 60601-1: 2005
- Electromagnetic Compatibility Testing per IEC 60601-1-2:2007
- Software Verification and Validation Testing in accordance with FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
- Sterilization Validation Testing on the Vacuum Line with Hydrophobic Filter per ISO 11135:2014
- Shelf-Life Testing on the Vacuum Line with Hydrophobic Filter, including:
  - Visual Inspection per ASTM F1886/F1886M-09,
  - Dye Penetration Test per ASTM F1929-15,
  - Seal Strength Test per ASTM F88/F88M-15, and
  - Mechanical Test (vacuum compatibility of the entire unit and tensile strength at joints) with justified acceptance criteria.

CONCLUSION:

The subject and predicate devices have the same indications for use and intended uses. Although there are differences in technological characteristics between the subject and predicate devices, these differences do not raise different questions of safety or effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.