June 12, 2019

CooperSurgical, Inc.
Christine Kupchick
Regulatory Affairs Associate
95 Corporate Drive
Trumbull, CT 06611

Re: K191291
Trade/Device Name: Wallace Dual Lumen Oocyte Recovery System
Regulation Number: 21 CFR§ 884.6100
Regulation Name: Assisted Reproduction Needles
Regulatory Class: II
Product Code: MQE
Dated: May 13, 2019
Received: May 14, 2019

Dear Christine Kupchick:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For
Sharon M. Andrews
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K191291

Device Name
Wallace Dual Lumen Oocyte Recovery System

Indications for Use *(Describe)*
The Wallace Dual Lumen Oocyte Recovery System is a sterile, single-use device for ultrasonic-guided transvaginal collection of oocytes from the ovarian follicles.

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.***

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CooperSurgical
Healthy women, babies, and families™

# 510(k) SUMMARY
# K191291

## SUBMITTER INFORMATION

Company Name: CooperSurgical Inc.
Company Address: 95 Corporate Drive
Trumbull, CT 06611

## CONTACT

Name: Christine Kupchick
Telephone: 203-601-5200 Ext. 3370
Fax: 203-601-9870
Email: christine.kupchick@coopersurgical.com

Date Prepared: June 10, 2019

## DEVICE IDENTIFICATION

Trade Name: Wallace Dual Lumen Oocyte Recovery System
Common Name: Oocyte Retrieval Needle
Regulation Number: 21 CFR 884.6100
Regulation Name: Assisted Reproduction Needles
Product Code: MQE (Needle, Assisted Reproduction)
Regulatory Class: Class II

## PREDICATE DEVICE INFORMATION

Wallace Dual Lumen Oocyte Recovery System (K182959).

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

## DEVICE DESCRIPTION

The Wallace Dual Lumen Oocyte Recovery System was previously 510(k) cleared under K182959. The current submission is for the addition of three 16-gauge needle models, in addition to the currently available 17-gauge needle models.

The Wallace Dual Lumen Oocyte Recovery System consists of a 33 cm dual lumen stainless steel needle with a plastic needle hub, and aspiration, flushing, and vacuum tubing. The needle hub acts as a handle and is designed for the user to hold between the thumb and index finger. It 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 the secondary lumen that is attached to the flushing tubing. The needle aspiration tubing connects to a silicone bung that allows connection to a sample tube. The silicone bung is also connected to the vacuum tubing that allows connection to a vacuum source.

The Wallace Dual Lumen Oocyte Recovery System is available in 16 or 17-gauge color-coded sizes (16G-Blue and 17G-Red). The needles are available in three aspiration tubing lengths: 500, 750, and 950 mm. The system includes flushing tubing of 700 mm length and vacuum tubing of 500 mm length. The device is provided sterile and is for single-use only.

## INDICATIONS FOR USE

The Wallace Dual Lumen Oocyte Recovery System is a sterile, single-use device for ultrasonic-guided transvaginal collection of oocytes from the ovarian follicles.

## SUBSTANTIAL EQUIVALENCE DISCUSSION

**Table 1: Substantial Equivalence Comparison**

| Attribute | Subject Wallace Dual Lumen Oocyte Recovery System | Predicate Wallace Dual Lumen Oocyte Recovery System |
|---|---|---|
| **Manufacturer** | CooperSurgical, Inc. | CooperSurgical, Inc. |
| **510(k) Number** | K191291 | K182959 |
| **Indications for Use** | The Wallace Dual Lumen Oocyte Recovery System is a sterile, single-use device for ultrasonic-guided transvaginal collection of oocytes from the ovarian follicles. | The Wallace Dual Lumen Oocyte Recovery System is a sterile, single-use devices for ultrasonic-guided transvaginal collection of oocytes from the ovarian follicles. |
| **Needle** | 33 cm dual lumen needle<br>16g and 17g sizes | 33 cm dual lumen needle<br>17g size only |
| **Needle Hub** | Molded with friction fit needle bosses and solvent bonded flushing side connector | Molded with friction fit needle bosses and solvent bonded flushing side connector |
| **Tubing Sets** | Aspiration: 500, 750, and 950 mm<br>Flushing: 700 mm<br>Vacuum: 500 mm | Aspiration: 500, 750, and 950 mm<br>Flushing: 700 mm<br>Vacuum: 500 mm |
| **Device Materials** | Stainless steel, methacrylate butadiene styrene (MBS), silicone, polyurethane, polycarbonate, Nylon, and acrylonitrile butadiene styrene (ABS) | Stainless steel, methacrylate butadiene styrene (MBS), silicone, polyurethane, polycarbonate, Nylon, and acrylonitrile butadiene styrene (ABS) |
| **Sterilization** | Ethylene oxide; SAL $10^{-6}$ | Ethylene oxide; SAL $10^{-6}$ |
| **Number of Uses** | Single-use; disposable | Single-use; disposable |
| **Shelf Life** | Two years | Two years |

The subject Wallace Dual Lumen Oocyte Recovery System and the predicate device (K182959) have identical Indications for Use statements; therefore, their intended uses are the same.

The subject and predicate device have different technological characteristics. The subject device is a line extension of the predicate device and includes the following modifications:

- Larger (16g) needle size
- Larger inner diameter of aspiration tubing

These differences identified do not raise different questions of safety and effectiveness as compared to the predicate.

### NON-CLINICAL PERFORMANCE TESTING

As part of demonstrating substantial equivalence to the predicate, a risk analysis was completed to identify risks associated with the device modifications (i.e., larger needle gauge and aspiration tubing inner diameter). Verification and validation testing were conducted to evaluate the modifications. The following tests, associated with the device modifications, were performed on the subject device according to methods and acceptance criteria outlined in the predicate device (K182959). The subject device passed all the testing in accordance with internal requirements and applicable standards to support substantial equivalence of the subject device:

- **Biocompatibility Testing per ISO 10993-1:2009**
    - Cytotoxicity per ISO 10993-5:2009
    - Irritation per ISO 10993-10:2010
    - Sensitization per ISO 10993-10:2010

- **Stability and Shelf Life**

  The following tests were completed after 2-years of accelerated aging per ASTM F1980-16:

    - Mouse embryo assay (MEA) - One-cell mouse embryos were incubated in extracts of the subject device and cultured at 37 °C. The percent of embryos developed to the expanded blastocyst stage within 96-hours was assessed in comparison to the control group. The acceptance criterion for the 1-Cell MEA was ≥80% embryos expanded to blastocyst at 96 hours.
    - Endotoxin - Evaluation performed using the Gel-Clot Limulus Amoebocyte Lysate (LAL) method per ANSI/AAMI ST72:2011 and USP <85>. The acceptance criterion was ≤ 20 EU/device.
    - Mechanical Performance Testing
        - Joint strength tensile testing
            - Aspiration tube to bung
            - Aspiration tube to needle/hub
        - Needle point penetration force testing
        - Needle stiffness

The following testing was leveraged from the predicate device (K182959). Test results from the predicate were used to support the subject device because the conditions were identical or the subject device modifications did not introduce a new worst-case configuration or scenario for testing.

- **Sterilization testing per ISO 11135:2014**
- **Ethylene oxide and ethylene chlorohydrin residual testing per ISO 10993-7: 2008 / (R)2012**
- **Simulated shipping and distribution testing per ISTA 3A:2008**
- **Package integrity testing**
    - Seal tensile strength per ASTM F88/F88M-15
    - Seal peel per ASTM F1886/F1866M-16
- **Leakage and fluid flow testing**

## CONCLUSION

The results of the testing described above demonstrate that the Wallace Dual Lumen Recovery System is as safe and effective as the predicate and supports a determination of substantial equivalence.