



Food and Drug Administration
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January 8, 2016

Cook Incorporated
Naomi Funkhouser
Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, IN 47404

Re: K151018
Trade/Device Name: Embryo Biopsy Pipette, Polar Body Biopsy Pipette, Testicular Sperm Extraction Pipette
Regulation Number: 21 CFR 884.6130
Regulation Name: Assisted Reproduction Microtools
Regulatory Class: Class II
Product Code: MQH
Dated: December 10, 2015
Received: December 11, 2015

Dear Naomi Funkhouser,

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,



Jeffrey W. Cooper -S
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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

Indications for Use

510(k) Number (if known)

K151018

Device Name

Embryo Biopsy Pipette

Polar Body Biopsy Pipette

Testicular Sperm Extraction Pipette

Indications for Use (Describe)

The Embryo Biopsy Pipette is intended to aspirate a blastomere or trophectoderm to diagnose genetic disorders prior to embryo selection.

The Polar Body Biopsy Pipette is intended to aspirate polar bodies to diagnose genetic disorders prior to embryo selection.

The Testicular Sperm Extraction Pipette is intended to extract sperm cells from biopsied testicular tissue.

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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5.0 510(k) Summary

Embryo Biopsy Pipette, Polar Body Biopsy Pipette, and Testicular Sperm Extraction Pipette

510(k) Summary

21 CFR §884.6130

Date Prepared: January 8, 2016

Submitted By:

Applicant: Cook Incorporated
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750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

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Contact Fax Number: 812-332-0281

Device Information:

Trade names: Embryo Biopsy Pipette
Polar Body Biopsy Pipette
Testicular Sperm Extraction Pipette
Common name: Microtools, Assisted Reproduction (Pipettes)
Classification Name: Assisted Reproduction Microtools
Regulation: 21 CFR §884.6130
Product Code: MQH

Predicate Devices:

The predicate device for the Embryo Biopsy and the Polar Body Biopsy is as follows:

- Cook's Pre-Implantation Genetic Diagnosis Pipettes (Biopsy Pipettes) (K033904)

The predicate device for the Sperm Extraction Pipettes is as follows:

- Cook's Intracytoplasmic Sperm Injection (ICSI), Micro-Injection Pipettes, Holding Pipettes, Denuding Pipettes, and Assisted Hatching/Zona Drilling Pipettes (K033903)

Device Description:

The Embryo Biopsy, Polar Body Biopsy, and Testicular Sperm Extraction Pipettes are 970 microns (μm) outer diameter borosilicate glass tubing that is bent and tapered. The Embryo Biopsy Pipette is tapered to a flat, smooth tip inner diameter of 30 μm and 35 μm . It is intended to be used for blastomere or trophectoderm aspiration. The Polar Body Biopsy Pipette is tapered to an inner diameter of 20 μm and beveled to a spike to assist in piercing through the zona pellucida to biopsy the polar body. The Testicular Sperm Extraction Pipette is tapered to a flat angle with an inner diameter of 6.5 μm . These pipettes are intended to extract sperm cells from biopsied testicular tissue. The device is supplied gamma sterilized and is intended for one-time use.

Intended Use:

The Embryo Biopsy Pipette is intended to aspirate a blastomere or trophectoderm to diagnose genetic disorders prior to embryo selection.

The Polar Body Biopsy Pipette is intended to aspirate polar bodies to diagnose genetic disorders prior to embryo selection.

The Testicular Sperm Extraction Pipette is intended to extract sperm cells from biopsied testicular tissue.

Comparison to Predicates:

The Embryo Biopsy Pipette and the Polar Body Pipette have the same intended use as K033904 – aspiration of embryo tissues/cells for genetic diagnosis.

The Testicular Sperm Extraction Pipette has the same intended use as K033903 - to manipulate sperm during ART procedures.

The proposed devices have the same technological characteristics (design material, comparable dimensions) as the predicate devices.

Performance Testing:

The Embryo Biopsy, Polar Body Biopsy, and Testicular Sperm Extraction Pipettes were subjected to testing to assure validation of design and performance as listed below. In addition, the Embryo Biopsy, Polar Body Biopsy, and Testicular Sperm Extraction Pipettes undergo MEA and LAL testing for each lot manufactured.

1. MEA Testing – The Embryo Biopsy, Polar Body Biopsy, and Testicular Sperm Extraction Pipettes underwent lot release Mouse Embryo Assay testing. The acceptance criterion was that $\geq 80\%$ 1 cell stage embryos must develop to blastocyst within 96 hours. The predetermined acceptance criterion was met.
2. LAL Testing – The Embryo Biopsy, Polar Body Biopsy, and Testicular Sperm Extraction Pipettes were lot-release tested using the Limulus Amebocyte Lysate (LAL) test. The devices must demonstrate < 20 EU/device. The predetermined acceptance criterion was met.
3. Functionality Study – The Embryo Biopsy Pipettes were tested to show evidence that glass pipettes fitted to a micromanipulator, micro-injector, and Micro-injector holder are capable of aspirating fluid without breaking or leaking. The predetermined acceptance criterion was met.
4. Shelf Life – The results of accelerated and real-time aging studies demonstrate that the subject devices maintain their sterility and functional performance characteristics over their proposed shelf life.
5. Sterilization Validation – Sterilization validation was performed in accordance with FDA recognized standards.

Conclusion:

The results of these tests support a conclusion that the Embryo Biopsy Aspiration, Polar Body Biopsy, and Testicular Sperm Extraction Pipettes are substantially equivalent to the predicate devices.