



Food and Drug Administration
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December 18, 2015

Cook Incorporated
Naomi Funkhouser
Regulatory Affairs Specialist
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402

Re: K150748
Trade/Device Name: Flexipet® Denuding Pipette, Flexipet® Manipulation Pipette
Regulation Number: 21 CFR 884.6130
Regulation Name: Assisted reproduction microtools
Regulatory Class: Class II
Product Code: MQH
Dated: November 18, 2015
Received: November 18, 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,

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

Indications for Use

510(k) Number (if known)

K150748

Device Name

Flexipet® Denuding Pipette and Flexipet® Manipulation Pipette

Indications for Use (Describe)

The Flexipet® Denuding Pipettes are intended to be used for blastomere or polar body manipulation, oocyte and embryo manipulation, or denuding.

The Flexipet® Manipulation Pipettes are intended to be used for blastomere or polar body manipulation, oocyte and embryo manipulation, blastocyst handling, and manipulation of the oocyte-cumulus complex.

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

Flexipet[®] Denuding Pipette
Flexipet[®] Manipulation Pipette
510(k) Summary
21 CFR §884.6130

Date Prepared: December 11, 2015

Submitted By:

Applicant: Cook Incorporated
Address: 750 Daniels Way
P.O. Box 489
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Phone Number: (812) 335-3575 x104371
Fax Number: (812) 332-0281

Contact: Naomi Funkhouser
Contact Address: Cook Incorporated
750 Daniels Way
P.O. Box 489
Bloomington, IN 47402
Contact Phone Number: (812) 335-3575 x104371
Contact Fax Number: (812) 332-0281

Device Information:

Trade name: Flexipet[®] Denuding Pipette
Flexipet[®] Manipulation Pipette
Common name: Microtools, Assisted Reproduction (Pipettes)
Classification Name: Assisted Reproduction Microtools.
Regulation: 21 CFR §884.6130
Product Code: MQH

Predicate Device:

The predicate device is "THE STRIPPER[®]" Micropipetter and Micropipetter Tips (Mid-Atlantic Diagnostics, Inc., K993699).

Device Description:

The Flexipet[®] Denuding Pipettes are polycarbonate tubes with inner diameters measuring 600 μm (microns) at the proximal end which taper in diameter in a range from 120 μm to 170 μm on the distal end. The micropipettes are all 3.5 inches in length and constructed from polycarbonate. The devices are supplied gamma sterilized and are intended for one-time use.

The Flexipet[®] Manipulation Pipettes are polycarbonate tubes with inner diameters measuring 600 μm (microns) at the proximal end which taper in diameter in a range from 80 μm to 600 μm on the distal end. The micropipettes are all 3.5 inches in length and constructed from polycarbonate. The devices are supplied gamma sterilized and are intended for one-time use.

Intended Use:

The Flexipet[®] Denuding Pipettes are intended to be used for blastomere or polar body manipulation, oocyte and embryo manipulation, or denuding.

The Flexipet[®] Manipulation Pipettes are intended to be used for blastomere or polar body manipulation, oocyte and embryo manipulation, blastocyst handling, and manipulation of the oocyte-cumulus complex.

Comparison to Predicates:

The Flexipet[®] Denuding Pipettes and Flexipet[®] Manipulation Pipettes are substantially equivalent to the predicate device, "THE STRIPPER[®]" Micropipetter and Micropipetter Tips (Mid-Atlantic Diagnostics, Inc., K993699), in that these devices have similar designs, methods of construction and operation, and indications for use.

Technological Characteristics:

The Flexipet[®] Denuding Pipettes and Flexipet[®] Manipulation Pipettes were subjected to testing as to assure validation of design and performance.

1. MEA Testing – The Flexipet[®] Denuding Pipettes and Flexipet[®] Manipulation Pipettes underwent lot-release Mouse Embryo Assay testing. The acceptance criterion was that $\geq 80\%$ 1-cell embryos developed to blastocyst within 96 hours. The predetermined acceptance criterion was met.
2. LAL Testing – The Flexipet[®] Denuding Pipettes and Flexipet[®] Manipulation 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. Cytotoxicity Testing – Testing was performed with the requirement that all test extracts must have a reaction grade of less than 2 (mild reactivity). The results showed that the predetermined acceptance criterion was met.
4. Accelerated Aging – After sterilization and accelerated aging, the devices remained flexible and did not become brittle; therefore, the acceptance criterion was met.
5. Pull-Out Force – Testing was performed with the requirement that the force needed to pull the pipette out of the aspiration tool must be a minimum of 0.4 lbf. The results showed that the predetermined acceptance criterion was met.
6. Aspiration Test – Fluid was aspirated through the Flexipet[®] Denuding Pipettes and Flexipet[®] Manipulation Pipettes using the Cook Flexipet[®] Adjustable Handle. The acceptance criterion was met.

Conclusion:

The results of these tests support a conclusion that the Flexipet[®] Denuding Pipettes and Flexipet[®] Manipulation Pipettes met the design input requirements based on the intended use and support the conclusion that these devices do not raise new questions of safety or effectiveness as compared to, and are substantially equivalent to, the predicate device, “THE STRIPPER[®]” Micropipetter and Micropipetter Tips, manufactured by Mid-Atlantic Diagnostics, Inc., cleared under 510(k) Premarket Notification Number K993699 on May 16, 2000.