510(k) SUMMARY

510(k) Number (if known): K092554

APR 30 2010

Submitter's Name: Sunlight Medical, Inc.

Address: 12443 San Jose Blvd, Suite 602,
Jacksonville, FL 32223

Telephone #: (904) 866-7978

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Contact person: Dunsong Yang

Date summary prepared: August 12, 2009, revised January 5, 2010

Device name:

Common / usual name: Preimplantation Genetic Diagnosis Pipettes
(Biopsy Pipettes)

Proprietary names: Blastomere Biopsy Pipettes
Polar Body Biopsy Pipettes

Classification name: Class II Assisted reproduction microtools
85MQH

CFR Reference: 884.6130

Predicate Devices:

The Blastomere Biopsy Pipettes and Polar Body Biopsy Pipettes to be manufactured by Sunlight Medical, Inc. are substantially equivalent to the Blastomere Biopsy Micropipets and Polar Body Micropipets (510K number: K012811) manufactured by Humagen Fertility Diagnostics, Inc., 2345 Hunter's Way, Charlottesville, VA 22901-7928. Specially, the Biopsy Pipettes are similar to other pipettes manufactured by Sunlight Medical and approved under K072600. The Biopsy Pipettes vary only by size and shape of the tip as determined by their usage as do the pipettes already approved. The material, manufacture process, testing and controls are the same.

Comparing to Humagen Blastomere Biopsy Micropipets, our Blastomere Biopsy Pipettes have a bigger variations in inner diameter (Sunlight 18-42 μm vs Humagen 28-42 μm). Other specifications, i.e., beveling and angulations, are the same.

Comparing to Humagen Polar Body Biopsy Micropipets, our Polar Body Biopsy Pipettes may have a spike draw on the tip. The inner diameter, beveling and angulations are the same.

Description of Device:

The Blastomere Biopsy Pipettes are very fine glass pipettes used in IVF/Assisted Reproduction Technology (ART) laboratories for the aspiration of blastomere(s) from embryos for the purpose of preimplantation genetic diagnosis. These pipettes have an inner diameters varying from 18-42 μm based customer's preferences and the stage of the embryos being biopsied. The tip may be flat or beveled at 45 degrees, then fire polished, and bended to 10 - 45 degrees or straight.

The Polar Body Biopsy Pipettes are very fine glass pipettes tools used in IVF/Assisted Reproduction Technology (ART) laboratories for the aspiration of polar bodies from oocytes and embryos for the purpose of preimplantation genetic diagnosis. These pipettes have an inner diameters varying from 13-15 μm. The tip may be flat or beveled at 45 degrees, then fire polished, and bended to 10 – 45 degrees or straight. Some of the tip may be pulled to form a sharp spike after polishing based customer's preferences.

These devices are intended for one-time use and will be marked sterile.

These devices are manufactured entirely from borosilicate glass. They are manufactured to specific sizes or the size may be modified to meet customer specifications, following procedures of the Sunlight Quality System. The final products are batch tested as part of a quality assurance program using Mouse Embryo Toxicity testing and endotoxin testing. The acceptance specifications of these tests are ≥80% of 2-cell mouse embryos to blastocysts and endotoxin ≤ 0.5 EU/device.

Indications for Use:

Blastomere Biopsy Pipettes: The intended use of the Blastomere Biopsy Pipettes is for removal of blastomere(s) from embryos, which may be done in order to perform preimplantation genetic diagnosis on the genetic material in the biopsied cell(s).

Polar Body Biopsy Pipettes: The intended use of the Polar Body Biopsy Pipettes is for removal of polar bodies from oocytes, which may be done in order to perform preimplantation genetic diagnosis on the genetic material in the biopsied cell(s).

These devices are to be used by professionals trained in assisted reproduction technologies (ART). Federal law restricts these devices to sale by or on the order of a physician.

Substantial Equivalence:

These devices will be manufactured according to specified process controls and a Quality Assurance Program. Being similar with respect to indications for use, materials and physical construction to predicate devices, these devices meet the requirements for section 510K substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

APR 30 2010

Dunsong Yang, M.D.
President/CEO
Sunlight Medical, Inc.
12443 San Jose Blvd, Suite 602
JACKSONVILLE FL 32223

Re: K092554
Trade/Device Name: Blastomere Biopsy Pipette and Polar Body Biopsy Pipette
Regulation Number: 21 CFR §884.6130
Regulation Name: Assisted reproduction microtools
Regulatory Class: II
Product Code: MQH
Dated: April 12, 2010
Received: April 13, 2010

Dear Dr. Yang:

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.

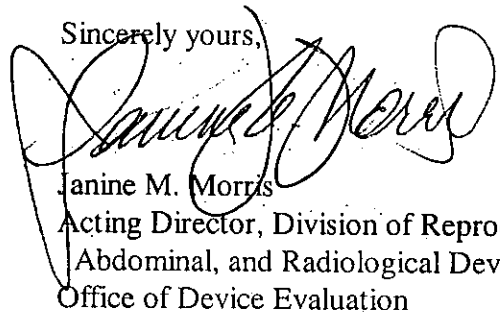
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,



Janine M. Morris
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K092554

Device name: Blastomere Biopsy Pipettes

Indications for Use:

The Blastomere Biopsy Pipettes are tools used in IVF/Assisted Reproduction Technology (ART) laboratories for removal of blastomere(s) from embryos, which may be done in order to perform preimplantation genetic diagnosis on the genetic material in the biopsied cell(s).

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K092554

Indications For Use

510(k) Number (if known): K092554

Device name: Polar Body Biopsy Pipettes

Indications for Use:

The Polar Body Biopsy Pipettes are tools used in IVF/Assisted Reproduction Technology (ART) laboratories for removal of polar bodies from oocytes, which may be done in order to perform preimplantation genetic diagnosis on the genetic material in the biopsied cell(s).

Prescription Use ___√___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
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