K012811

FEB 11 2002

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name: Humagen Fertility Diagnostics, Inc.

Address: 2400 Hunter's Way
Charlottesville, VA 22911

Telephone #: (434) 979-4000

FAX #: (434) 295-5912

Contact person: Cindy Showalter

Date summary prepared: August 21, 2001

Device name:

Classification name: Assisted reproduction microtools
85 MQH
CFR# 884.6130

Common/Usual name: Micropipets used for retrieval of embryonic or blastomere cells for purposes of preimplantation genetic diagnosis

Proprietary names: Blastomere Biopsy Micropipet
Polar Body Biopsy Micropipet

Substantial Equivalence:

The biopsy micropipets submitted for approval are similar to other micropipets manufactured by Humagen and approved under K990847. It is the understanding of Humagen that the usage of the micropipets differs from those approved under the previous 510K submission, and that the FDA currently has not approved or cleared the tests for which these micropipets are used. The biopsy micropipets vary only by size and shape of the tip as determined by their usage as do the micropipets already approved. Testing and controls are the same.

Description of Device:

Biopsy Micropipets are used to remove polar bodies from the zygote (polar body) or blastomeres from the embryo (blastomere biopsy) for the purpose of preimplantation genetic diagnosis. These devices are manufactured from borosilicate glass on which 2 cell mouse embryo and endotoxin testing are performed. They are manufactured

following procedures of the Humagen Quality System. The pipets are manufactured to specific sizes or the size may be modified to meet customer specifications.

Intended use statement:

The blastomere biopsy and polar body biopsy micropipets intended use is for polar body or blastomere biopsy, which may be done in order to perform pre-implantation genetic diagnosis on the genetic material in the biopsied cell(s). Individual laboratories currently develop and determine performance characteristics for their own use. It is understood that the FDA has not currently cleared or approved these procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2002

Ms. Cindy Showalter
Quality Assurance Manager
Humagen Fertility Diagnostics, Inc.
2400 Hunter's way
CHARLOTTESVILLE VA 22911

Re: K012811
Trade/Device Name: Polar Body and Blastomere Biopsy micropipets
Regulation Number: 21 CFR 884.6130
Regulation Name: Assisted reproduction microtools
Regulatory Class: II
Product Code: 85 MQH
Dated: November 12, 2001
Received: November 13, 2001

Dear Ms. Showalter:

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.

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); 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.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) number (if known): K012811

Device Name: Polar body biopsy micropipet
Blastomere biopsy micropipet

Indications for use:

Biopsy micropipets are used to aspirate polar bodies or blastomeres containing genetic material for the purpose or pre-implantation genetic diagnosis. These devices are intended for single use and will be supplied sterile. The labeling will contain the following statement, in prominent and boxed format:

> *"This tool is indicated for embryo or blastomere biopsy, which may be done in order to perform preimplantation genetic diagnosis (PGD) on the genetic material in the biopsied cell(s). Tests for PGD are currently developed and their performance characteristics are determined by individual laboratories for their own use. The performance of these tests may vary depending on the particular assay and disease evaluated. Currently these tests have not been cleared or approved by the Food and Drug Administration."*

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012811