JUL 14 1999

K990847

510(k) SUMMARY

Submitter's Name: Humagen Fertility Diagnostics, Inc.

Address: 2400 Hunter's Way
Charlottesville, VA 22911

Telephone #: (804) 979-4000

FAX #: (804) 295-5912

Contact person: Cindy Showalter

Date summary prepared: May 28 , 1999

Device name:

Classification name: Assisted reproduction microtools (per CFR# 884.6130)

Common/Usual name: Micropipets used for in vitro fertilization

Proprietary names: Intracytoplasmic Sperm Injection Micropipets (ICSI)
Spermatid ICSI Micropipets
Holding Micropipets
Assisted Hatching Micropipets
Subzonal Injection Micropipets (SUZI)
Partial Zona Dissection Micropipets (PZD)
Denuding Micropipets

Substantial Equivalence:

Substantial equivalence is being supported by the Federal Register Notice Final Rule entitled "Obstetric and Gynecologic Devices; Reclassification and Classification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures. This equivalence is supported by the SUMMARY statement:

> Upon the effective date, the Federal Register document may be cited in the absence of an existing predicate device which would be used to support substantial equivalence.

Description of Device:

Micropipets are fabricated from 1 mm. diameter borosilicate glass capillary tubes. One end of the glass tube is pulled to a much smaller diameter using a glass puller with a heated coil. Diameters range from 2 - 3 um to 200 um depending upon the type of micropipet. Most micropipets are ground on a microgrinder to produce a beveled or flat opening. Generally, a sharp spike is pulled on beveled micropipets by touching the bevel to a heated glass bead and withdrawing quickly. Angles may be added along the shaft of the micropipet per request of the end user to best fit their micromanipulation equipment. Specifications for each variation of micropipet is as follows:

Intracytoplasmic Sperm Injection Micropipets (ICSI) – pulled to a 6 to 7 um outer diameter, 4 to 5 um inner diameter with a 35 or 50 degree bevel and a short, sharp point or may be made with no point. May be straight or with an angle (15 – 45 degrees as specified), 0.5mm from the beveled end. Any of these parameters may be modified to meet customer specifications.

Spermatid ICSI Micropipets - pulled to a 9 um outer diameter, 7 to 8 um inner diameter with a 35 or 50 degree bevel and a short, sharp point at the tip. May be

straight or with an angle (15 to 45 degrees as specified), 0.5 mm from the beveled end. Again, parameters may vary somewhat depending on customer specifications.

Holding Micropipets – one end is pulled to the specified outer diameter, which can range from 65 um to 180 um, scored and cut to yield a blunt opening of the appropriate size, and polished over a hot glass bead to a 20 to 25 um inner diameter opening, unless otherwise specified. Small holding micropipets are pulled to an outer diameter of 65 to 95 um, medium holdings are pulled to an outer diameter of 100 to 120 um, large holdings are pulled to an outer diameter of 125 to 150 um, and extra large holding micropipets are pulled to an outer diameter of 155 to 180 um. Holding micropipets may be angled or straight.

Assisted Hatching Micropipets – one end is pulled to a standard outer diameter of 8 to 10 um unless otherwise specified, with a blunt opening. Other outer diameter sizes are available upon request. Assisted hatching micropipets may be straight or angled (15 to 45 degrees as specified), 0.5 mm from the tapered end.

Subzonal Insertion Micropipets (SUZI) – one end is pulled to a 10 to 12 um outer diameter with a 40 degree bevel, and a short, sharp point at the tip. SUZI micropipets may be straight or angled (15 to 45 degrees as specified), 0.5 mm from the tapered end.

Partial Zona Dissection Micropipets (PZD) - one end is pulled to a long, thin taper with a closed, sharp point. PZD micropipets may be straight or angled (15 to 45 degrees as specified), 0.5 mm from the tapered end.

Denuding Micropipets – one end is pulled and then cut with a diamond knife to an opening of 150 or 190 um inner diameter with a blunt opening.

Testing Procedures:

Each lot of micropipets is mouse embryo tested for toxicity. We use a two-cell mouse embryo bioassay. A two-cell mouse embryo test was performed as follows: 25 ul tissue culture medium containing serum albumin and penicillin/streptomycin was overlaid with 1 ml mineral oil and equilibrated overnight in 5.5% CO_2. On the morning of the embryo harvest, a droplet of medium was exposed to product and embryos were cultured in the media beginning at the two-cell stage. Control droplets of medium were not exposed to product before receiving embryos. The combined percent of embryos developing to expanded and/or hatching blastocysts were assessed at 72 hours of culture. Embryos exposed to the pipets are considered non-toxic if the number of expanded and/or hatching blastocysts in the treated group is within 10% of the control group, and no contamination of the culture has occurred. Greater than 80% hatching/expanded blastyocysts in the control group indicates a valid assay.

Sterilization is performed by gamma radiation. The sterilization validation program follows ANSI/AAMI/ISO 11137-1995 procedures. Quarterly dose audits are conducted by an outside testing laboratory by AAMI Method 1.

The sterility assurance level for the micropipets is 10^{-6}.

The minimum established radiation dose is 21.8 kGy established by AAMI Method 1, SIP. A maximum limit of 40 kGy has been established based upon the physical characteristics of the materials.

Each lot of micropipets is also tested for endotoxin levels using the Limulus Amebocyte Lysate assay. The level of endotoxin units per device must be less than 20 to be considered acceptable.

Intended use statement:

The micropipet family's intended use is to manipulate zygotes during the ICSI procedure.

The micropipets are used in the tissue culture techniques performed by embryologists when injecting a single sperm into an egg, or assisting an embryo in hatching prior to reimplantation.

The micropipets are tools used in procedures that have been developed to aid infertile couples achieve pregnancy. Specifically, the ICSI procedure is beneficial in cases where the male fertility is impaired.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 14 1999

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

Re: K990847
Intracytoplasmic Sperm Injection
Micropipets (ICSI)
Dated: May 31, 1999
Received: June 2, 1999
Regulatory Class: II
21 CFR §884.6130/Procode: 85 MQH

Dear Ms. Showalter:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K990847

DEVICE NAME: Intracytoplasmic Sperm Injection Micropipets (ICSI)

INDICATIONS FOR USE:

The micropipet family's indication for use is to manipulate zygotes during the ICSI procedure.

Micropipets are used in the tissue culture techniques performed by embryologists when injecting a single sperm into an egg, or assisting an embryo in hatching prior to re-implantation.

The micropipets are tools used in procedures that have been developed to aid infertile couples achieve pregnancy. Specifically, the ICSI procedure is beneficial in cases where the male fertility is impaired.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use____
(Per 21 CFR 801.109) (Optional Format 1-2-96

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K990847