JUL 14 1999

K990941

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 labware (per CFR# 884.6160)

Common/Usual name: ICSI Tissue Culture Dish

Proprietary names: NewLife™ Dish

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:

NewLife Dishes are fabricated from polysterene and are 60 mm. diameter. Dishes are made with or without clear lids, etched or unetched. Etched dishes have a center circle with 8 smaller circles inside the larger circle, and a 9^{th} circle inside the 8 circles. There are numbers 1 through 8 outside the large circle, with the number 1 at the top of the dish. Unetched dishes have center circles, but no other circles are etched on the dishes. Dishes are disposable, intended for one time use only.

Testing Procedures:

Each lot of New Life dishes 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, medium was exposed to product and embryos were cultured in the media beginning at the two-cell stage. For NewLife Dishes, the MEA is performed in the test dish, providing continuous exposure. 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 dishes 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 blastoycysts in the control group indicates a valid assay.

Each lot of dishes 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.

Each lot of dishes is sterilized by gamma radiation with a sterility assurance level of 10^{-6}. Quarterly dose audits are performed to insure the sterility assurance level is maintained or following each batch sterilization if less often than quarterly.

The packaging to maintain device sterility consists of a pouch made from INTEGRA® Peel K packaging. This is a reinforced, heavy-weight 70 lb. paper coated with a sealant, designed for medical device packaging applications. The package is heat-sealed. This packaging has been tested to ensure a microbial barrier, and has been validated to maintain sterility for a shelf life of 2 years.

Intended use statement:

The NewLife Dish's intended use is to hold zygotes/embryos during micromanipulation or other tissue culture procedures in the IVF laboratory.

New Life Dishes 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 dishes are disposable tissue culture labware used in procedures that have been developed to aid infertile couples achieve pregnancy. Specifically, the ICSI procedure is beneficial in cases where the male infertility 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: K990941
Newlife Dish
Dated: May 31, 1999
Received: June 2, 1999
Regulatory Class: II
21 CFR §884.6160/Procode: 85 MQK

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): K990941 [redacted]

DEVICE NAME: NewLife Dish

INDICATIONS FOR USE:

The NewLife Dish's indication for use is to hold zygotes/embryos during micromanipulation or other tissue culture procedures in the IVF laboratory.

NewLife Dishes 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 dishes are disposable tissue culture labware used in procedures that have been developed to aid infertile couples achieve pregnancy. Specifically, the ICSI procedure is beneficial in cases where the male infertility 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 X (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

Prescription Use V (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K990941